IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

YOLONDA BAILEY; CRYSTAL CAMPOS; JOLENE DURAN; RYAN FRAUSTO; CRYSTAL GOODWIN; JASON LONG; LEANN HARRIS; LISAMARIE ROFFO; NETTIE HUSKEY; TYKIA BROWN; KIMBERLY LEE; DAHNE FARERI; KAMICA WARNOCK; and MAHALA HOLMES, Plaintiffs, vs. BAYER, CORP.; BAYER HEALTHCARE, LLC; BAYER ESSURE, INC.; BAYER HEALTHCARE PHARMACEUTICALS, INC.; and BAYER A.G., Defendants.	NO.: JURY TRIAL DEMANDED

CONSOLIDATED CIVIL COMPLAINT

NOW COMES Plaintiffs YOLANDA BAILEY, CRYSTAL CAMPOS, JOLENE DURAN, RYAN FRAUSTO, CRYSTAL GOODWIN, JASON LONG, LEANN HARRIS, LISAMARIE ROFFO, NETTIE HUSKEY, TYKIA BROWN, KIMBERLY LEE, DAHNE FARERI, KAMICA WARNOCK, and MAHALA HOLMES, who in filing this Consolidated Complaint seek judgment against Defendants BAYER CORP.; BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER HEALTHCARE, LLC; BAYER ESSURE, INC.; and BAYER A.G. (hereinafter collectively referred to as "Defendants") for the personal injuries they sustained as a result of being prescribed, receiving, and subsequently using the defective and unreasonably dangerous permanent birth control device Essure®. At all times relevant hereto, Essure® was manufactured, designed, formulated, tested, packaged, labeled, produced, created,

made, constructed, assembled, marketed, advertised, distributed, and sold by Defendants or Conceptus, Inc., which was acquired by Defendants on or about April 28, 2013.

I

INTRODUCTION

1. This civil action is asserted by Plaintiffs who relied to their detriment on Defendants' express warranties as to the safety and effectiveness of the permanent birth control device, Essure®. As a result of Defendants' negligence and Plaintiffs' detrimental reliance on Defendants' warranties that Essure® was safe and effective, Plaintiffs have suffered a range of injuries, including, but not limited to, ectopic pregnancy, full-term pregnancy, pregnancy loss, perforation of organs, device migration, hysterectomies, severe abdominal and menstrual pain, pain during intercourse, heavy bleeding, migraines, back pain, depression, fatigue, weight fluctuation, and autoimmune diseases.

2. In November 2002, the FDA granted Essure® Conditional Premarket Approval ("CPMA"). However, this CPMA has since become invalid and Essure® an adulterated product as Defendants violated several of the conditions imposed by the FDA. Defendants failed to submit annual follow-ups for women who participated in original clinical trials, failed to conduct post-approval studies, and failed to report complaints of adverse events to the FDA. Most notably, Defendants failed to notify the FDA of their internal records of over 16,000 complaints regarding Essure®. Defendants also used misleading and false advertising in marketing Essure® as they misrepresented results of clinical trials and post-CPMA trials.

3. Further, Defendants have been cited by the FDA for (1) failing to report and actively concealing eight perforations caused by Essure®; (2) erroneously using non-conforming material in manufacturing Essure®; (3) failing to use pre-sterile and post-sterile cages in

manufacturing Essure®; and (4) manufacturing Essure® for years at an unlicensed manufacturing facility. As such, Defendants' violations not only invalidated the CPMA for Essure® but also endangered Plaintiffs' lives and the safety of the public.

II

PARTIES, JURISDICTION AND VENUE

4. Plaintiff YOLANDA BAILEY is a citizen of Philadelphia, Pennsylvania.

5. Plaintiff CRYSTAL CAMPOS is a citizen of Fort Morgan, Colorado.

6. Plaintiff JOLENE DURAN is a citizen of Aurora, Colorado.

7. Plaintiff RYAN FRAUSTO is a citizen of Tinley Park, Illinois.

8. Plaintiff CRYSTAL GOODWIN is a citizen of Overton, Nevada.

9. Plaintiff JASON LONG is a citizen of Overton, Nevada.

10. Plaintiff LEANN HARRIS is a citizen of North Las Vegas, Nevada.

11. Plaintiff LISAMARIE ROFFO is a citizen of Douglassville, Pennsylvania.

12. Plaintiff NETTIE HUSKEY is a citizen of Zap, North Dakota.

13. Plaintiff TYKIA BROWN is a citizen of Norfolk, Virginia.

14. Plaintiff KIMBERLY LEE is a citizen of Gilbert, Arizona.

15. Plaintiff DAHNE FARERI is a citizen of Westville, New Jersey.

16. Plaintiff KAMICA WARNOCK is a citizen of Trotwood, Ohio.

17. Plaintiff MAHALA HOLMES is a citizen of Rochester, New York.

18. BAYER CORP. is a for-profit corporation that was incorporated in the state of Indiana, with its principal place of business in the Commonwealth of Pennsylvania at 100 Bayer Road, Building 4, Pittsburgh, Pennsylvania 15205. As such, Defendant is authorized to do and does business through the Commonwealth of Pennsylvania.

19. BAYER CORP. is the parent corporation of BAYER HEALTHCARE, LLC, BAYER ESSURE, INC., and BAYER HEALTHCARE PHARMACEUTICALS, INC. (the "Bayer subsidiaries"). BAYER CORP. owns 100 percent of the Bayer subsidiaries.

20. BAYER CORP. is wholly owned by BAYER A.G.

21. BAYER A.G. is a German for-profit corporation. Defendant BAYER A.G. is authorized to do and does business throughout the Commonwealth of Pennsylvania.

22. At all times relevant herein, the BAYER subsidiaries are agents or apparent agents of BAYER CORP. and/or BAYER A.G. As such, each Defendant acted as agents of the other Defendants and acted within the course and scope of the agency regarding the acts and omissions alleged. Additionally, Defendants together acted in concert and/or abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of enriching themselves and creating an injustice at the expense of Plaintiffs.

23. Further, the Bayer subsidiaries, individually and/or collectively, are "Alter Egos" of BAYER CORP. and/or BAYER A.G. as, *inter alia*, they are wholly owned by BAYER CORP; share the same trademark; share management and officers; and in other ways were dominated by BAYER CORP.

24. Moreover, there exists and at all times relevant herein there existed a unity of interest in ownership among all Defendants such that individuality and separateness between and among them has concluded. Since Defendants are "Alter Egos" of one another and exert control over each other, adherence to the fiction of separate existence of these Defendants as entities distinct from one another will permit an abuse of the corporate privilege, sanction fraud and promote injustice. BAYER CORP. and BAYER A.G. wholly ignored the separate status of the Bayer subsidiaries and so dominated and controlled its affairs that its separate entities were a

sham.

25. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC., is a for-profit corporation incorporated in the state of Delaware. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.'s headquarters are located at 100 Bayer Boulevard, Whippany, New Jersey. Defendant is authorized to and does business throughout the Commonwealth of Pennsylvania.

26. Defendant BAYER HEALTHCARE, LLC, is a for-profit corporation incorporated in the state of Delaware. Defendant BAYER HEALTHCARE, LLC's headquarters are located at 100 Bayer Boulevard, Whippany, New Jersey. Defendant is authorized to and does business throughout the Commonwealth of Pennsylvania.

27. Defendant BAYER ESSURE, INC., is a for-profit corporation incorporated in the state of Delaware. Defendant BAYER ESSURE, INC.'s headquarters are located at 100 Bayer Boulevard, Pittsburgh, Pennsylvania. Defendant is authorized to and does business throughout the Commonwealth of Pennsylvania.

28. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because district courts "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States" and though the causes of action alleged herein are rooted in state law, Plaintiff alleges that Defendants failed to 1) meet regular reporting requirements, 2) report known hazards to the Food and Drug Administration ("FDA"), and 3) comply with federal laws regarding marketing and distribution of the Essure® device, thereby invalidating the Premarket Approval and making distribution of the Essure® device and sale to the Plaintiffs illegal under the Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301, *et seq.* The Court also has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

29. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(2) and (3) because a substantial part of the events or omissions giving rise to the claim occurred in this district, and Defendants regularly transact substantial business in this district and are subject to personal jurisdiction in this district. Additionally, Defendants have advertised in this district and have received substantial revenue and profits from their sales of Essure® devices in this district; therefore, a substantial part of the events and/or omissions giving rise to the claims occurred, in part, within this district.

30. This Court has personal jurisdiction over Defendants because they have conducted substantial business in this judicial district, and intentionally and purposefully placed the Essure® devices into the stream of commerce within Pennsylvania and throughout the United States.

III

PLAINTIFFS' HISTORIES

31. As discussed in depth below, each of the Plaintiffs in this case has sustained serious physical injuries as a result of being implanted with the permanent birth control device, Essure®. Accordingly, as a result of (1) Defendants' negligence described *infra*; and (2) Plaintiffs' reliance on Defendants' warranties, Defendants' Essure® devices have caused Plaintiffs serious personal injuries. As such, Plaintiffs have suffered a range of injuries, such as ectopic pregnancy, actual pregnancy, abdominal pain, depression, fatigue, heavy bleeding, pain during intercourse, weight fluctuations, severe back pain, and migraines. Additionally, some Plaintiffs' Essure® devices have migrated, perforated, and even become embedded in areas outside of the fallopian tubes. Moreover, some Plaintiffs have been forced to undergo hysterectomies in an effort to have their Essure® devices removed.

A. PENNSYLVANIA

1. Yolanda Bailey

32. Plaintiff Yolonda Bailey is a resident of Philadelphia, Pennsylvania.

33. In or about January 2007, Plaintiff Bailey underwent the Essure® procedure at a clinic located in Philadelphia, Pennsylvania.

34. Plaintiff Bailey learned she was pregnant in October 2015, which was approximately seven (7) years after being implanted with Essure®. Plaintiff Bailey had an HSG performed three (3) months after implantation of the Essure® device which confirmed that her fallopian tubes were completely blocked.

35. Plaintiff's pregnancy was a cervical ectopic pregnancy. As such, Plaintiff was informed that she would have to take drugs to induce miscarriage as carrying an ectopic pregnancy to term is extremely dangerous and could have caused Plaintiff's untimely death. Accordingly, it was necessary to induce Plaintiff's miscarriage in order to save her life.

36. Plaintiff Bailey's physician explained that this ectopic pregnancy was the result of the migration of the Essure® device that was implanted on her right side, and which she describes as "dangling out of the [right fallopian] tube."

37. On or around December 1, 2015, Plaintiff Bailey underwent a right tubal ligation during which the Essure® micro-insert in her right fallopian tube was removed. However, the Essure® device implanted in Plaintiff's left fallopian tube remains in her body.

38. Plaintiff Bailey also suffers severe menstrual and abdominal pain.

39. Since receiving Essure®, Plaintiff Bailey has also suffered from depression, weight fluctuation, coital pain, and heavy bleeding.

40. Plaintiff Bailey now experiences migraines—of which she had no history prior to receiving Essure®.

41. Prior to undergoing implantation of Essure®, Plaintiff Bailey received a brochure that attested to the safety and effectiveness of Essure® as a permanent birth control device. In relying on Defendants' misrepresentations as to the safety and effectiveness of Essure®, Plaintiff decided to undergo the implantation of the Essure® device. As a result, Plaintiff Bailey now suffers from ongoing severe menstrual and abdominal pain, heavy bleeding, migraines, weight fluctuation, and depression. Further, Plaintiff Bailey would not have had to endure a painful ectopic pregnancy and subsequent miscarriage, nor would she have been forced to undergo surgical tubal ligation had she not relied on Defendants' misrepresentations as to the safety and effectiveness of the Essure® device.

2. Lisamarie Roffo

42. Plaintiff Lisamarie Roffo is a resident of Douglassville, Pennsylvania.

43. On or around March 21, 2013, Plaintiff Roffo underwent the Essure® procedure performed by Dr. Melissa Dubois at The Reading Hospital and Medical Center located in West Reading, Pennsylvania.

44. Plaintiff Roffo's physician suggested that she consider undergoing the Essure® procedure after she gave birth to her son.

45. After being implanted with Essure®, Plaintiff Roffo began to suffer hair loss, vision loss, rashes, severe bloating, severe abdominal and back pain, and pain during intercourse.

46. Moreover, Plaintiff Roffo was recently diagnosed as having clinical depression and also suffers from fatigue since being implanted with the Essure® device.

47. Plaintiff Roffo has lost most of her teeth since being implanted with the Essure® device and as such has been forced to get a full set of dentures.

48. Plaintiff Roffo has suffered irregular menstrual cycles that are accompanied by heavy bleeding and blood clotting. Additionally, Plaintiff Roffo now regularly experiences headaches, bloating, and mood swings.

49. When Plaintiff Roffo first explained her symptoms to her doctors, they initially suspected her symptoms were brought about by menopause. However, as the symptoms worsened, her doctor told her to come in for an examination to determine whether Plaintiff's symptoms were the result of a fibroid cyst.

50. Plaintiff Roffo went to the doctor's office on or about August 10, 2015, for a hysterosonogram in order to determine if the symptoms she was experiencing were caused by a fibroid cyst. However, during this hysterosonogram, it was discovered that one of her Essure® devices had migrated.

51. On or about August 28, 2015, Plaintiff Roffo underwent a hysteroscopy, bilateral tubal ligation, and right cystectomy as a result of the migration of the Essure® micro-insert placed in her left fallopian tube. Further, during this procedure, Plaintiff Roffo's doctors determined that Plaintiff Roffo also had a complex ovarian cyst which had caused dysfunctional uterine bleeding.

52. Although Plaintiff Roffo was originally supposed to undergo a bilateral removal of the Essure® devices, during the procedure doctors were unable to remove the left coil as it could not be found in her fallopian tube.

53. Subsequently, on or about November 9, 2015, Plaintiff Roffo underwent a total hysterectomy performed by Dr. Jaylaine Ghoubrial at The Reading Hospital and Medical Center

located in West Reading, Pennsylvania. During this procedure, Plaintiff Roffo's uterus, cervix and left fallopian tube were all removed. Despite undergoing this total hysterectomy, Plaintiff's chronic pain has continued and as such, Plaintiff Roffo is still consulting with doctors to determine her next medical treatment measures.

54. Most recently, Plaintiff Roffo's doctor ordered an MRI to determine if any coil pieces remain in her body.

55. Plaintiff Roffo recalls reviewing a brochure for Essure® in the lobby of her doctor's office. Plaintiff Roffo relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. As a result of undergoing the implantation of Essure®, Plaintiff Roffo now suffers from hair and vision loss, rashes, severe bloating, and dysfunctional uterine bleeding. Further, as a result of being implanted with Essure® Plaintiff Roffo had to undergo bilateral surgical tubal ligation, right cystectomy, and hysterectomy. Plaintiff Roffo would not have chosen to undergo implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

B. COLORADO

1. Crystal Campos

56. Plaintiff Crystal Campos is a resident of Fort Morgan, Colorado.

57. In or about May 2013, Plaintiff Campos underwent the Essure® procedure at Colorado Plains Medical Center performed by Dr. Michelle Soriano.

58. Plaintiff Campos became pregnant approximately four months after the Essure® device was implanted.

59. Plaintiff Campos learned that she was pregnant one month after undergoing a hysterosalpingogram ("HSG"), the results of which determined that her Essure® micro-inserts were in the correct location and that her fallopian tubes were completely blocked.

60. Plaintiff Campos was very upset upon learning that she was pregnant after having the Essure® device implanted, as she was led to believe the device was a permanent form of birth control.

61. Plaintiff Campos delivered a daughter on June 21, 2014.

62. Plaintifff Campos underwent surgical tubal ligation on June 22, 2014, as a result of her failed Essure® devices.

63. Upon information and belief, the Essure® micro-inserts were not removed during Plaintiff Campos's surgical tubal ligation and, therefore, currently remain in Plaintiff Campos's body.

64. In addition to becoming pregnant, giving birth to her daughter, and subsequently undergoing surgical tubal ligation, Plaintiff Campos has also suffered severe menstrual and abdominal pain.

65. Plaintiff Campos has also experienced excessive bleeding during her menstrual period. Plaintiff's blood flow has become so heavy that she is now required to wear two tampons and a large pad during her menstrual periods.

66. Since being implanted with Essure®, Plaintiff Campos has also seen a fluctuation in her weight and often suffers from nausea.

2. Jolene Duran

67. Plaintiff Jolene Duran is a resident of Aurora, Colorado.

68. In or about August 2009, Plaintiff Duran underwent the Essure® procedure performed by Dr. Heather Mattick at Denver Health Medical Center, located in Denver, Colorado.

69. After being implanted with Essure®, Plaintiff Duran began suffering severe menstrual and abdominal pain in addition to severe back pain. In fact, Plaintiff Duran's pain continued to worsen to the point that Plaintiff Duran was prescribed muscle relaxers in addition to being given cortisone shots to help manage her severe pain.

70. Since undergoing the implantation of Essure®, Plaintiff Duran has suffered from depression and fatigue.

71. Plaintiff Duran has endured heavy bleeding, pain during intercourse, and migraines—of which she had no prior history before being implanted with Essure®.

72. Most significantly, the Essure® device implanted in Plaintiff Duran's left fallopian tube has migrated and perforated her fallopian tube, distorting to such an extent that it is now in the shape of the letter "N," as revealed by x-ray examination.

73. Plaintiff Duran recalls being given an Essure® brochure by her doctor that promoted the Essure® as a safe and effective permanent birth control device. Plaintiff Duran relied on the representations in the brochure in choosing to have the Essure® implanted.

C. ILLINOIS

1. Ryan Frausto

74. Plaintiff Ryan Frausto is a resident of Tinley Park, Illinois.

75. On December 14, 2006, Plaintiff Frausto had the Essure® device implanted at Magna Surgical Center in Chicago, Illinois. Her gynecologist, Dr. Kenneth Finkelstein, is the

physician who initially recommended Essure® to Plaintiff. Dr. Finkelstein is also the physician who performed Plaintiff Frausto's Essure® procedure.

76. Plaintiff Frausto had an HSG performed on July 23, 2007, to confirm that the Essure® devices were in place and adequately blocking her fallopian tubes.

77. Shortly after placement of Essure®, Plaintiff Frausto started to experience severe lower back pain. At first, Plaintiff Frausto thought that her lower back pain was caused by the epidural she received while in labor a few months earlier. However, Plaintiff Frausto's lower back pain continued to worsen to such a degree that Plaintiff Frausto began seeing a chiropractor to help with her pain management. Plaintiff Frausto had never experienced such severe lower back pain prior to receiving Essure®.

78. Additionally, Plaintiff Frausto began to suffer heavy bleeding, which concerned her to the point of contacting Dr. Finkelstein's office. Again, Dr. Finkelstein informed her that the heavy bleeding she was experiencing was normal.

79. Plaintiff eventually underwent an endometrial ablation on December 18, 2009, to try and control her heavy bleeding.

80. After undergoing the ablation, Plaintiff's bleeding continued, thus prompting her to return to Dr. Finkelstein's office. During this visit, an x-ray of the pelvis was taken and it was noted that the left Essure® device could not be visualized. Plaintiff Frausto was informed that she would need to undergo a hysterectomy in order to remove a large fibroid that had developed in her uterus.

81. On or around February 7, 2012, Plaintiff Frausto underwent a total hysterectomy at Little Company of Mary, located in Evergreen Park, California. During the procedure it was

noted that the right Essure® device appeared "distorted" upon removal. The left Essure® device was not present in the left tube and remains somewhere in Plaintiff Frausto's body.

82. Plaintiff Frausto continues to suffer from severe back pain, heavy bleeding, and headaches. The location of the left Essure® device in her body is currently unknown.

D. NEVADA

1. Crystal Goodwin

83. Plaintiff Crystal Goodwin is a resident of Overton, Nevada.

84. In or about September 2013, Plaintiff Goodwin underwent the Essure® procedure which was performed by Dr. Luu at Elite Women's Health.

85. Approximately three years after the Essure® device was implanted, Plaintiff Goodwin learned she was pregnant. Plaintiff Goodwin did not undergo an HSG, as she was never informed by her doctor that she needed to have this done.

86. Plaintiff Goodwin's doctors have since determined that her right fallopian tube was blocked but that her left fallopian tube is now abnormally coiled. As a result of the abnormal coiling of Plaintiff Goodwin's left fallopian tube, doctors are unable to find the Essure® device that was originally placed in Plaintiff Goodwin's left fallopian tube.

87. Plaintiff Goodwin's doctors are unable to inform her as to how the failed Essure® device will affect her pregnancy.

88. Plaintiff Goodwin is currently in her second trimester and reports experiencing morning sickness and back pain which grew more severe when Plaintiff Goodwin was approximately six or seven weeks pregnant.

89. Plaintiff Goodwin and her husband are extremely concerned as to how her implanted Essure® coil, which doctors have been unable to find, will affect her pregnancy and ultimately the delivery and health of the couple's unborn child.

90. In addition to becoming pregnant three years after being implanted with Essure®, Plaintiff Goodwin suffered, and continues to suffer, severe abdominal, back, and side pain. Plaintiff Goodwin also suffers from migraines, of which she had no prior history before Essure®.

91. Plaintiff Goodwin's relationship with her husband has deteriorated since she was implanted with Essure®, as she has been unable to provide service and society to her husband as she was once able to prior to receiving Essure®. Specifically, whereas Plaintiff Goodwin was once happy and healthy prior to being implanted with Essure®, she is now emotionally detached from her husband as a result of her unexpected pregnancy, and experiences severe pain, stress, and fatigue since undergoing the Essure® procedure. Further, the couple's level of sexual intimacy has sharply declined since Plaintiff Goodwin underwent the Essure® procedure as she continues to suffer severe pain during intercourse.

92. As such, since being implanted with Essure®, Plaintiff Goodwin is no longer able to tend to everyday household chores such as cleaning, performing yard work, driving, or running errands as a result of her constant severe pain. Additionally, Plaintiff Goodwin is no longer able to pick-up the couple's now two-year-old son, which interferes with her parenting responsibilities.

93. Prior to becoming pregnant, Plaintiff Goodwin suffered severe menstrual pain accompanied by heavy bleeding.

94. Plaintiff Goodwin recalls being given a brochure promoting Essure® as being a safe and effective form of permanent birth control. Plaintiff Goodwin relied on Defendants'

misrepresentations as to the safety and effectiveness of Essure®. Specifically, Plaintiff Goodwin remembers feeling as though she was being talked into undergoing implantation of Essure® as she was told it was less evasive and a "better" choice than tubal ligation. Plaintiff Goodwin would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

2. Jason Long

95. Plaintiff Jason Long is a resident of Overton, Nevada.

96. Plaintiff Long is married to Plaintiff Goodwin and has suffered a loss of consortium as a result of his wife's injuries.

97. Specifically, Plaintiff Long's relationship with Plaintiff Goodwin changed within a few weeks of Plaintiff Goodwin undergoing the Essure® procedure. Plaintiff Long noticed that Plaintiff Goodwin was experiencing mood swings, severe pain, and a dramatic decline in her desire for sexual intimacy. Plaintiff Long initially believed these symptoms were a natural part of the healing process, however, the longer they persisted the more he grew concerned.

98. Whereas Plaintiff Long's wife was happy and healthy prior to being implanted with Essure®, she is emotionally detached from her husband as a result of her unexpected pregnancy, severe pain, stress, and fatigue since undergoing the Essure® procedure. Additionally, the couple's level of sexual intimacy has sharply declined since Plaintiff Long's wife underwent the Essure® procedure, as she continues to suffer severe pain during intercourse.

99. Since being implanted with Essure®, Plaintiff Long's wife is no longer able to tend to everyday household chores such as cleaning, performing yard work, driving or running

errands as a result of her constant pain. Additionally, Plaintiff Long's wife is no longer able to pick-up the couple's now two-year-old son, which interferes with her parenting responsibilities.

100. Plaintiff Long and his wife are seriously concerned as to how her implanted Essure® coils, which doctors have been unable to find, will affect her pregnancy and ultimately the delivery and health of the couple's unborn child.

3. Leann Harris

101. Plaintiff Leann Harris is a resident of North Las Vegas, Nevada.

102. On or about August 1, 2014, Plaintiff Harris underwent the Essure® procedure, which was performed by Dr. Gregory Gex at St. Rose Dominican Hospital located in Las Vegas, Nevada.

103. After being implanted with Essure® Plaintiff Harris endured an ectopic pregnancy, which subsequently led to the removal of a fallopian tube on or around March 26, 2015.

104. While the Essure® devices were implanted, Plaintiff Harris suffered severe menstrual pain accompanied by heavy blood loss. Plaintiff Harris also suffered severe abdominal and back pain, as well as pain during intercourse.

105. To treat her chronic pain, Plaintiff Harris has been prescribed Percocet and Lyrica.

106. Plaintiff Harris now suffers from fatigue and depression.

107. After her tube was removed, Plaintiff Harris's symptoms continued to worsen. Plaintiff's doctor performed an ultrasound that revealed that a micro-insert had become embedded in her uterus that required the removal of Plaintiff Harris's uterus, on or about October 23, 2015. Plaintiff Harris's ovaries remain intact.

108. Prior to opting to receive the Essure® device, Plaintiff Harris reviewed a tri-fold brochure from her doctor which promoted Essure® as a safe and effective permanent birth control device. Relying on Defendants' misrepresentations as to the safety and effectiveness of Essure®, Plaintiff Harris decided to undergo the implantation of Essure®. Plaintiff Harris would not have chosen to undergo the implantation of Essure® but for Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

E. North Dakota

1. Nettie Huskey

109. Plaintiff Nettie Huskey is a resident of Zap, North Dakota.

110. On or about March 31, 2015, Plaintiff Huskey underwent the Essure® procedure performed by Dr. Erica Hofland at Sanford Health Dickinson Clinic located in Dickinson, North Dakota.

111. After being implanted with Essure®, Plaintiff Huskey began to suffer severe menstrual, abdominal, and back pain.

112. Plaintiff Huskey has suffered from heavy bleeding during her menstrual cycle and pain during intercourse since undergoing the implantation of the Essure® device.

113. Plaintiff Huskey suffers from fatigue as a result of Essure®.

114. Plaintiff Huskey's chronic pain became so severe that she was prescribed Hydrocodone in order to treat it.

115. After having the Essure® devices implanted for less than a year, Plaintiff Huskey sought to have both Essure® devices removed. Accordingly, on or about December 1, 2015, Plaintiff Huskey underwent laparoscopic removal of both Essure® devices.

116. Despite the removal of her Essure® devices, Plaintiff's painful symptoms continue to persist.

117. Plaintiff Huskey reviewed an Essure® brochure that promoted Essure® as a safe and effective permanent birth control device. At the time Plaintiff Huskey reviewed the Essure® brochure, she was waiting for her appointment with her doctor, specifically for the purpose of discussing her options for permanent birth control. After reviewing this brochure containing Defendants' misrepresentations as to the safety and effectiveness of Essure®, Plaintiff Huskey decided to undergo the Essure® procedure. Plaintiff Huskey would not have opted to be implanted with the Essure® devices had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

F. Virginia

1. Tykia Brown

118. Plaintiff Tykia Brown is a resident of Norfolk, Virginia.

119. Sometime in 2012, Plaintiff Brown underwent implantation of Essure® performed at the Eastern Virginia Medical School, located in Norfolk, Virginia.

120. After being implanted with Essure®, Plaintiff Brown developed severe menstrual and abdominal pain, pain during intercourse, and weight fluctuation. Plaintiff Brown also began to suffer migraines, of which she had no prior history.

121. Plaintiff's menstrual cycles would continue for ten to fifteen days at a time and would cause Plaintiff to suffer heavy blood loss. In fact, Plaintiff's menstrual periods would cause her to lose such a large quantity of blood that she would have to undergo iron supplement treatment.

122. Plaintiff Brown's chronic pain became so severe that she was prescribed Norco and ibuprofen as treatment.

123. Plaintiff Brown was informed that the only way doctors would be able to remove Essure® was if she underwent a hysterectomy.

124. Accordingly, on or about February 29, 2016, Plaintiff underwent a hysterectomy, during which it was determined that her Essure® devices had migrated. Plaintiff's cervix, uterus and fallopian tubes were all removed, leaving her ovaries intact.

125. Plaintiff Brown originally intended to undergo tubal ligation as permanent birth control and was in the hospital and had signed paperwork for a tubal ligation. However, after speaking with a nurse who told Plaintiff Brown about the benefits of Essure®, and its safety and effectiveness, she instead opted to undergo the Essure® procedure.

G. Arizona

1. Kimberly Lee

126. Plaintiff Kimberly Lee is a resident of Gilbert, Arizona.

127. In or about January 2011, Plaintiff Lee underwent the Essure® procedure performed by Dr. Joseph Lindstrom at his medical offices, located in Mesa, Arizona.

128. After undergoing the implantation of Essure®, Plaintiff Lee developed chronic pain, which she continues to suffer daily even though the Essure® micro-inserts have since been removed.

129. Approximately three months after being implanted with Essure®, Plaintiff Lee had an HSG performed to confirm that her fallopian tubes were blocked.

130. After undergoing implantation of Essure®, Plaintiff Lee was diagnosed with rheumatoid arthritis. Dr. Lindstrom determined that Essure® was responsible for causing her rheumatoid arthritis and Plaintiff Lee had the Essure® micro-inserts removed in December 2014.

131. Plaintiff Lee filed a complaint to the FDA reporting the adverse effects she endured after undergoing the implantation of Essure®.

132. As a result of being implanted with Essure®, Plaintiff Lee continues to suffer daily from chronic pain. Moreover, since having Essure® implanted, Plaintiff now must undergo extensive medical treatment for her rheumatoid arthritis.

H. New Jersey

1. Dahne Fareri

133. Plaintiff Dahne Fareri is a resident of Westville, New Jersey.

134. In or about September 2011, Plaintiff Fareri underwent the Essure® procedure performed by Dr. Joseph Riley at Vineland Hospital[1] located in Vineland, New Jersey.

135. Approximately three months after undergoing the implantation of Essure®, Plaintiff had an HSG performed to confirm that her fallopian tubes were blocked. After the HSG was performed, Plaintiff recalls being told that her Essure® micro-inserts were in place and that she should not have any problems moving forward.

136. Thereafter, Plaintiff Fareri began experiencing irregular menstrual periods, during which she would experience severe blood clotting. Plaintiff Fareri's blood clots grew to such an extent that she endured severe pain with each passing blood clot.

[1] Vineland Hospital has since changed its name to Inspira Medical Center Vineland.

137. Plaintiff Fareri underwent dilation and curettage,[2] as well as an ablation to stop her heavy bleeding and blood clots. After performing these procedures, Plaintiff Fareri was advised to start taking oral birth control.

138. After being implanted with Essure®, Plaintiff also suffered severe menstrual and abdominal pain, pain during intercourse, weight fluctuation, and fatigue.

139. Plaintiff Fareri also experienced migraines on an almost daily basis prior to the removal of the Essure® device. Plaintiff Fareri's migraine pain grew so severe that she was prescribed gabapentin.

140. On or about March 11, 2016, Plaintiff Fareri underwent a hysterectomy to have Essure® removed. Plaintiff's hysterectomy was performed by Dr. Salerno at Kennedy Hospital located in Township, New Jersey. After undergoing this procedure, Plaintiff Fareri was prescribed Vicodin to treat her subsequent pain.

I. OHIO

1. Kamica Warnock

141. Plaintiff Kamica Warnock is a resident of Trotwood, Ohio.

142. In or about September 2007, Plaintiff Warnock underwent the implantation of Essure® at Miami Valley Hospital located in Dayton, Ohio.

143. Plaintiff Warnock subsequently had an HSG performed, which confirmed that Plaintiff's fallopian tubes had been blocked, rendering her incapable of becoming pregnant.

144. Nevertheless, Plaintiff Warnock unexpectedly became pregnant in 2014 and experienced high blood pressure during this pregnancy.

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[2] A procedure that is performed in order to remove tissue from inside the uterus, so as to treat certain uterine conditions, such as heavy bleeding.

145. On October 23, 2014, Plaintiff Warnock gave birth to a baby boy, who was diagnosed with cystic fibrosis just one week after his birth.[3]

146. This pregnancy occurred because Plaintiff Warnock's Essure® device migrated from her fallopian tubes.

147. Since being implanted with Essure®, Plaintiff Warnock has suffered severe menstrual and abdominal pain that became so severe that she was prescribed Percocet, Tramadol, and Ibuprofen (800 mg).

148. Since being implanted with Essure®, Plaintiff Warnock has suffered heavy bleeding during her menstrual periods. In 2010, Plaintiff Warnock was hospitalized after suffering significant blood loss during her menstrual period.

149. As a result of undergoing the Essure® procedure, Plaintiff Warnock has suffered depression, fatigue, and weight fluctuation. She also began suffering from migraines, of which she had no prior history.

150. After the birth of her son, in late 2014, Plaintiff Warnock underwent a hysterectomy, including the removal of her fallopian tubes, in order to have both Essure® micro-inserts removed from her body.

151. Plaintiff Warnock was shown an Essure® brochure by her doctor while he described the Essure® device and procedure. Specifically, she remembers the brochure promoting Essure® as a safe, permanent birth control device. As such, this particular Essure® brochure strongly emphasized the device's permanence. Plaintiff Warnock relied on the

[3] According to the Centers for Disease Control, "[c]ystic fibrosis (CF) is a chronic, progressive and frequently fatal genetic (inherited) disease of the body's mucus glands. CF primarily affects the respiratory and digestive systems in children and young adults. The sweat glands and the reproductive system are also usually involved. On the average, individuals with CF have a lifespan of approximately 30 years."

representations in the brochure concerning the safety, effectiveness, and permanence of the Essure® device.

J. NEW YORK

1. Mahala Holmes

152. Plaintiff Mahala Holmes is a resident of Rochester, New York.

153. In or about November 2013, Plaintiff Holmes underwent the Essure® procedure performed by Dr. Colby Previte at Highland Hospital, located in Rochester, New York.

154. After undergoing the implantation of Essure®, Plaintiff Holmes began to suffer severe menstrual, abdominal, and back pain. Plaintiff Holmes continues to suffer from depression, fatigue, heavy menstrual bleeding, pain during intercourse, weight fluctuation, and chronic itching and pain in her pelvic region.

155. Since being implanted with Essure® Plaintiff has been diagnosed with an allergy to nickel—the metal compound from which Essure® is manufactured.

156. Plaintiff Holmes was also diagnosed with an autoimmune disorder as the result of being implanted with Essure®.

157. Further, Plaintiff underwent a number of sonograms to determine what was causing her pain and bleeding. In or around May 2015, Plaintiff Holmes underwent a hysterectomy performed by Dr. Kara Eastwood at Parkridge Hospital, located in Rochester, New York.

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IV

FACTUAL BACKGROUND

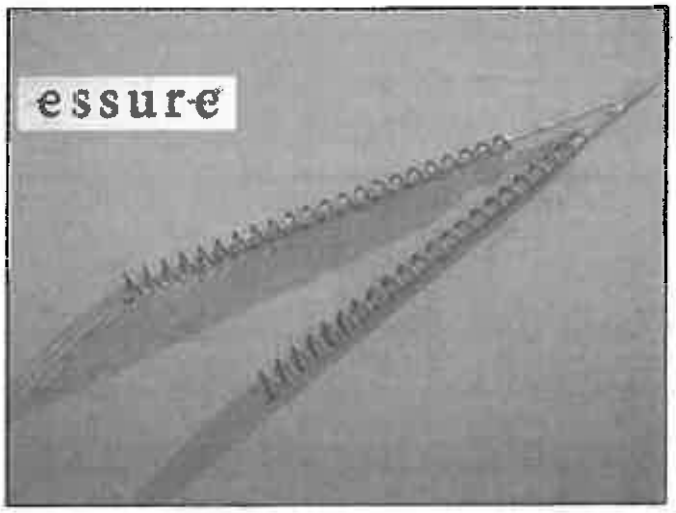
A. WHAT IS ESSURE?

158. Essure® is promoted as a fast and permanent form of non-surgical birth control that is threaded through the vaginal opening and inserted into a patient's fallopian tubes.

159. As a method of birth control, Essure® functions by causing bilateral occlusion of the fallopian tubes – a blockage of the fallopian tubes in order to prevent sperm from fertilizing the patient's eggs.

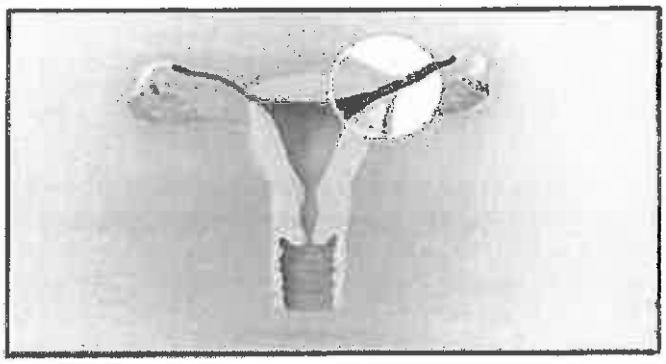
160. The Essure® product consists of an introducer, delivery catheter, and two micro-inserts.

161. The Essure® micro-inserts are small spring-like devices composed of a stainless steel inner coil, a nickel titanium (Nitinol) expanding outer coil, and polyethylene terephthalate (PET) fibers, which are wound in and around the inner coil.



162. During the Essure® placement procedure, while using an hysteroscope, the physician inserts the Essure® micro-inserts through the patient's vagina, cervix, uterus and ultimately implants the micro-inserts into the patient's fallopian tubes, "where [the device] elicits

an inflammatory reaction and response which, over time, leads to occlusion of the fallopian tubes by tissue ingrowth."



163. Essure® begins to function as birth control once the scar tissue forms around the implanted Essure® micro-inserts, thus creating an occlusion of the fallopian tubes that sperm cannot penetrate.

164. For three months following insertion of the devices, patients are warned that another form of birth control is necessary to prevent pregnancy because it takes approximately that amount of time for scar tissue to form around the Essure® implants.

165. After three months, a dye is injected into the patient's uterus and then the doctor performs a hysterosalpingogram ("HSG"), which is a special x-ray procedure that confirms that the patient's fallopian tubes are indeed blocked or occluded. Once the results of the HSG have confirmed that the patient's fallopian tubes are successfully blocked by Essure®, the patient is advised to cease using alternative forms of birth control.

B. REGULATORY BACKGROUND

166. Essure® was originally designed and manufactured by Conceptus, Inc. ("Conceptus"), which was acquired by Defendant Bayer AG, on or around April 28, 2013, and is now wholly-owned by Bayer. Accordingly, for purposes of this lawsuit, Conceptus and

Defendants are one and the same and will be referred to collectively as "Defendants" throughout the remainder of the Complaint.

167. Essure® is a Class III medical device that is now manufactured, sold, distributed, marketed, and promoted by Defendants.

168. Defendants trained physicians on how to use the Essure® device and other hysteroscopic equipment.

169. Prior to the sale of Conceptus to Defendant Bayer AG, Conceptus applied for and was granted Conditional Premarket Approval ("CPMA") for Essure® by the FDA, subject to a number of conditions.

170. Premarket Approval ("PMA") is the FDA process of scientific and regulatory review in evaluating the safety and effectiveness of Class III medical devices. According to the FDA, Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present unreasonable risk of illness or injury. As such, Premarket Approval grants the applicant permission to market the device.

171. According to FDA regulations, the agency is provided 180 days to review the PMA submission and to make its determination as to whether to grant permission to market the device. Prior to approving or denying PMA, the appropriate advisory committee may review the PMA submission at a public meeting and provide the FDA with its recommendations on whether the FDA should approve the submission in question.

172. Accordingly, a Class III device that fails to meet the requirements for CPMA is considered an adulterated device under section 501(f) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and as such, cannot be marketed.

173. During the Premarket Approval Process, devices can either be "approved," "conditionally approved," or "not approved."

174. On November 4, 2002, the Essure™ System was only "conditionally approved," as evidenced in the conditions set forth in the premarket approval order for Essure®.

175. The FDA stated in the CPMA Order for Essure® that "[f]ailure to comply with the conditions of approval invalidates this approval order."

176. The FDA's CPMA Order placed the following conditions on its approval of Essure®:

a. Annual follow-ups with the women who participated in the Phase II and Pivotal clinic trials are to be submitted **annually for 5 years**, "[i]n order to gather long-term safety and effectiveness data on the Essure™ System";

b. **Post-approval study** in the U.S. with newly trained physicians reporting:

   1. "rates of successful bilateral placement of the Essure™ System at first attempt"; and

   2. "identification of factors predictive of failure to achieve bilateral placement of the Essure™ System at first attempt."

c. Adverse reaction or device defect reporting "**within 10 days** after the applicant receives or has knowledge of information;" and

d. "**[R]eport to the FDA** whenever [Conceptus] receives or otherwise become[s] aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer":

   1. "May have caused or contributed to a death or **serious injury**"; or

2. "Has **malfunctioned** and such device "would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

177. Despite the fact that failure to comply with just one of these conditions would serve to invalidate the CPMA Order for Essure®, Defendants failed to comply with several of the conditions imposed by the order. Specifically:

i. Defendants **failed to timely provide the FDA with reports** after twelve months, eighteen months, and then a final report for one schedule. Additionally, all reports failed to meet their respective deadlines.

ii. Defendants failed to document successful implantation of Essure®, thus concealing the failure rates of Essure®.

iii. Defendants failed to notify the FDA of several adverse reactions and thus, actively concealed the same. As such, Defendants **failed to report eight perforations** that resulted from use of Essure® and were cited for the same by the FDA via Form 483.[4]

iv. Defendants also failed to report to the FDA information they received that reasonably suggested that the device may have caused or contributed to a serious injury, thus concealing such injuries. As mentioned above, Defendants failed to report **eight perforations** caused by Essure® to the FDA as evidenced in Form 483.

v. Defendants failed to provide the FDA with notice of their *internal* records consisting of **16,047 complaints** regarding Essure®.

[4] Form 483 is issued to firm management at the conclusion of inspection when an FDA investigator has observed any conditions that violate the FDCA rendering the device "adulterated."

vi. Defendants' warranties were not truthful or accurate.

vii. Defendants' warranties were not consistent with applicable federal and state law.

178. The CPMA also required Defendants to comply with sections 502(q) and (r) of the FDCA which prohibit offering Essure® "for sale in any State, if its advertising is false or misleading."

179. As described below under "Facts and Warranties," Defendants violated both sections 502(q) and (r) by falsely and misleadingly advertising Essure® to Plaintiffs and their respective physicians. Nevertheless, Defendants continued to sell Essure® with misleading and false advertising in further violation of the CPMA Order.

180. According to the FDA, "a PMA may be sold to another company," but "the sponsor must submit a PMA amendment to notify the FDA of the new owner [stating] the effective date of ownership transfer; a statement of the new owner's commitment to comply with all conditions of approval applicable to the PMA; and either a statement that the new owner has a complete copy of the PMA including all amendments, supplements, and reports or a request for a copy from the FDA files."

181. Accordingly, there were 36 PMA supplements filed with the FDA regarding Essure®. However, **not one of these 36 PMA supplements included notification of the new owner, Defendant Bayer.**

182. As such, (1) the CPMA is invalid per the FDA; (2) Essure® is considered an "adulterated" product that cannot be marketed or sold per the FDA given Defendants' numerous violations of conditions imposed in the CPMA order; and (3) the invalid CPMA was not properly transferred to Bayer and, thus, Defendants do not have a valid PMA for Essure®.

C. CLINICAL TRIALS

183. As was set forth in the Summary of Safety and Effectiveness Data, the Center for Devices and Radiological Health ("CDRH") granted expedited review of the CPMA for Essure® because "it offers significant advantages over existing approved alternatives for permanent birth control. Namely, the Essure™ System is delivered hysteroscopically without general anesthesia or an abdominal incision."

184. Between November 1998 and June 2001, a total of 745 women underwent the Essure® placement procedure in two separate clinical investigations so as to evaluate the safety and effectiveness of the Essure™ System (227 in the Phase II study and 518 women in the Pivotal trial).

185. Defendants reported to the FDA that the majority of women in *both* clinical trials "experienced moderate pain during and immediately following the procedure, and the majority of women experienced spotting for an average of 3 days after the procedure."

186. However, Defendants reported to the FDA that after just one year following implantation of Essure®, approximately 4 percent of the women who participated in the clinical trials reported having abdominal pain and 9 percent reported back pain.

187. When the FDA granted CPMA for Essure®, it was clear to state that the "data from these two clinical effectiveness studies are based on only 1-year and 2-year follow-up[s]." As such, the FDA concluded that "[t]he risks of long term implantation are unknown. This is of special significance with respect to pregnancy, including ectopic pregnancy."

188. Accordingly, the FDA required a 5-year follow-up under the Phase II and Pivotal trials "[i]n order to gather long-term safety and effectiveness data on the Essure™ System. . ."

189. In its CPMA Order, the FDA specifically required Conceptus "to follow participants who [were] relying on Essure® for contraception for both safety and effectiveness at 2, 3, 4, and 5 years after *discontinuation of alternative contraception.*"

190. Additionally, the FDA stated that the data collected should include pregnancies and outcomes; adverse events; and histological explant data following any extirpative surgeries.

191. In the CPMA letter, the FDA concluded that when a five-year follow-up report was submitted, the agency would have to determine whether continued follow-up of these study subjects is required.

192. Further, the FDA required Conceptus to submit three (3) copies of an Adverse Reaction Report or Device Defect Report to the PMA Document Mail Center within 10 days after it received or had knowledge of the information concerning any adverse reactions, side effects, injuries, toxicity, or sensitivity reaction attributable to the Essure® device.

193. As of October 2013, there were only 943 complaints about Essure® to the FDA whereas 750,000 Essure® procedures had been performed worldwide at the time.

194. The initial clinical trials that provided effectiveness and safety data, and upon which the CPMA relied were the "Phase II" trial and the larger "Pivotal" study.

195. In the Phase II study, the following adverse or other events that delayed or prevented reliance on Essure® for contraception were initially reported: perforation (2.9%); expulsion (0.5%); other unsatisfactory micro-insert location (0.5%); and initial tubal patency (3.5%). Additionally, during this study, 0.9% of women reported experiencing pain.

196. In the Pivotal Trial, the following adverse or other events that delayed or prevented reliance on Essure® for contraception were initially reported: perforation (1.1%);

expulsion (2.9%); other unsatisfactory micro-insert location (0.6%); and initial tubal patency (3.5%). Additionally, during this study 12.9% of women reported experiencing pain.

197. However, the most frequently reported adverse events in the first year that did not prevent women from relying of Essure™ were back pain (9.0%), abdominal pain/cramps (3.8%) and dyspareunia (3.6%).

198. Additionally, the FDA reported that while the following adverse events were not experienced by women who participated in clinical studies, they were still possible:

i. pregnancy, including ectopic pregnancy, in women relying on the Essure™ device;

ii. perforation of internal bodily structures other than the uterus and fallopian tube;

iii. adnexal infection/salpingitis;

iv. adverse events associated with the hysterosalpingogram (HSG) or x-rays;

v. the effect of future medical procedures that involve the uterus or fallopian tubes on the ability of the Essure™ micro-insert to provide protection against pregnancy;

vi. adverse events associated with surgery attempting to reverse the Essure™ procedure, as well as adverse events associated with pregnancy following a reversal procedure or an *in vitro* fertilization (IVF) procedure; and

vii. adverse events associated with gynecologic surgical procedures (e.g., endometrial ablation).

199. In the FDA's Summary of Safety and Effectiveness Data, the perforations experienced by women in the first year were explained as being caused by the "since-discontinued support catheter," which is now no longer a part of the Essure™ System.

D. POST-MARKET SUREVEILLANCE

200. From 2013-2015, complaints to the FDA concerning Essure® jumped from 943 to over 9,000.

201. After examining safety concerns raised by patients and cited in the Medical Device Reports ("MDR's") for Essure®, the FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee on September 24, 2015.

202. During this meeting, the Committee was "asked to provide input regarding the need for product labeling changes, the collection of additional post-market safety data, or other mitigation steps, and the overall benefit-risk profile of the [Essure] device based on current available information."

203. The FDA's review of available information after the September 2015 Advisory Committee Meeting resulted in the following:

i. the FDA specifically ordered Bayer to conduct a postmarket surveillance study to obtain more data about Essure's benefits and risks;

ii. the FDA required that a boxed warning and Patient Decision Checklist be added to Essure® product labels to ensure that a woman receives and understands information regarding the benefits and risks of this type of device prior to undergoing the Essure® procedure; and

iii. the FDA issued draft guidance, "Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization" to provide the public with

an opportunity to comment on the proposed language to be included in these warnings.

204. The FDA is also in the process of completing its evaluation of the trade complaint filed regarding allegations initially made in a Citizen Petition. The allegations include clinical trial misconduct, notably that **clinical trial participants' medical records were altered to reflect more favorable data on participants' experiences**, and that Defendants violated the terms of the PMA approval order and violated the laws that related to the manufacturing and marketing of Essure®.

205. In fact, the FDA inspected Bayer as part of its ongoing complaint investigation and Bayer provided the FDA with available case report forms that documented patient experiences during Essure® clinical trials.

206. During the FDA's inspection of Bayer, it allegedly found that less than 1% of case report form data pertaining to pain, bleeding, device placement/movement and pregnancy were changed during the clinical trials.[5]

207. Bayer must now follow a post-market surveillance study protocol, which must be submitted within 30 days of the FDA's announcement and the study must begin within 15 months of the protocol being determined. The **FDA is requiring Bayer to follow at least 2,000 women for at least 3 years in order to determine the risks of general tubal ligation versus Essure®**. Additionally, Bayer is required to provide interim reports.

[5] However, according to Defendants' own statement made in response to the FDA requiring post-market surveillance of Essure®, "[a]lthough modifications to the case report forms were identified, the FDA's analysis did not find evidence that the sponsor purposefully modified patient responses to reflect more favorable data for Essure." Thus, indicating that at least some modifications were indeed made to case report forms during the clinical trials.

208. Although **Bayer claimed to have only 943 complaints about Essure® as of 2013**, the database for Manufacturer and User Facility Device Experience ("MAUDE"), as maintained by the FDA, paints a very different picture.

209. In fact, according to the FDA, there have been approximately **9,900 complaints** from November 4, 2002, through December 31, 2015. The most common complaints were as follows: abdominal pain (6,989); heavier or irregular periods (3,210); headaches (2,990); fatigue (2,159); and weight fluctuations (2,088).

210. The most frequent device problems reported were: patient-device incompatibility[6] (2,016); migration of the device or device component (854); device operating differently than expected (490); device breakage (429); device difficult to remove (280); malposition of the device (199); and device difficult to insert (187).

211. Further, there have been 32 reports coded by the submitter as resulting in death. Of these 32 complaints, six appear to have been incorrectly coded, as there was no indications of death in the report. Of the remaining 26 complaints, six related to **four adult deaths**; 18 reports related to **15 incidents of pregnancy loss**; and two reports related to **two incidents of a death of an infant after live birth**.

212. Additionally, the FDA has received **631 reports of pregnancies** in patients with Essure®. Of these, **150 were reported to have resulted in a live birth**, 204 did not indicate whether the pregnancy resulted in a live birth or pregnancy loss; and **294 resulted in pregnancy loss**.

[6] For example, a patient being allergic to nickel. Although, during the FDA panel on Obstetrics and Gynecology Devices, it was discussed that further studies were needed to determine the prevalence of such reactions.

213. Among the 294 reports of women who experienced a pregnancy loss, 96 were reported as ectopic pregnancies; 43 were reported as elective terminations of pregnancies, and 155 were other pregnancy losses.

E. FAILURE TO ADEQUATELY TRAIN PHYSICIANS

214. Upon information and belief, Plaintiffs allege that Defendants (1) failed to adequately train implanting physicians on how to use the Essure® delivery system; (2) provided specialized hysteroscopic equipment manufactured by a third party; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing on and monopolizing the birth control market at the expense of Plaintiffs' safety and well-being.

215. Because Essure® was the first device of its kind, the implanting physicians were trained by Defendants on how to properly insert the micro-inserts using the disposable delivery system and were given hysteroscopic equipment by Defendants.

216. In fact, to capture the market, Defendants independently undertook a duty of training physicians, including the implanting physicians, on how to properly use (1) its own mechanism of delivery, and (2) the specialized hysteroscopic equipment manufactured by a third party.

217. As to Essure®, Defendants' Senior Director of Global Professional Education stated, "training is the key factor when clinicians choose a new procedure" and "[f]or the Essure® procedure, the patient is not under anesthesia, therefore a skilled approach is crucial."

218. In fact, because gynecologists and Plaintiffs' implanting physicians were unfamiliar with the device and how to deliver it, Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses—where Defendants observed physicians until Defendants believed they were competent;

(4) created Essure® Procedure Equipment Supplies Checklists; and (5) represented to Plaintiffs that "Physicians must be signed-off to perform Essure® procedures."

219. Defendants provided no training to the implanting physicians on how to *remove* Essure® should it migrate.

220. Defendants also kept training records on all physicians "signed-off to perform Essure® procedures."

221. In order to sell its product, and because the implanting physicians did not have access to the expensive hysteroscopic equipment, Defendants provided the implanting physicians with hysteroscopic equipment which, although not part of Essure®, is necessary for implanting Essure®. As such, the entrustment of this equipment is not part of any CPMA.

222. Defendants entered into agreements with Johnson & Johnson Co., Olympus America, Inc., Richard Wolf Medical Instruments Corp., and Karl Storz Endoscopy, America, Inc., (1) to obtain specialized hysteroscopic equipment to then give to physicians and (2) to increase its sales force to promote Essure®.

223. According to Defendants, these agreements allowed Defendants to "gain market presence . . . and expand . . . market opportunity by driving adoption among a group of physicians."

224. In regard to the entrustment of such specialized equipment, Defendants admitted: "We cannot be certain how successful these programs will be, if at all."

225. Defendants handed out this equipment to unqualified physicians, including Plaintiffs' implanting physicians, in their effort to sell Essure®.

226. Defendants knew or failed to recognize that the implanting physician was not qualified to use such specialized equipment, yet provided the equipment to the unqualified implanting physician in order to capture the market.

227. In return for providing the hysteroscopic equipment, Defendants required that the implanting physicians purchase two Essure® "kits" per month. Accordingly, this was part of Defendants' unreasonably dangerous and negligent distribution plan aimed solely at capturing market share with reckless disregard for the safety of the public and Plaintiffs.

228. Defendants' distribution plan included requiring implanting physicians to purchase two Essure® "kits" per month, regardless of whether he or she used them. This distribution plan created an environment which induced the implanting physicians to "push" Essure® and implant the same into Plaintiffs.

229. Accordingly, Defendants used the expensive hysteroscopic equipment to induce the implanting physicians into an agreement as "bait." Once the implanting physicians "took the bait," they were required to purchase two Essure® "kits" per month, regardless of whether the physician sold any Essure® "kits."

230. This was an unreasonably dangerous distribution scheme as it compelled implanting physicians to sell two devices per month at the expense of Plaintiffs' health, safety, and well-being.

231. Defendants' distribution plan also included (1) negligently distributing Essure® against FDA orders and sections 501(f), 502(q) and (r) of the FDCA by marketing and selling an adulterated product; (2) the promotion of Essure® through representatives of the hysteroscopic equipment manufacturers, who were neither adequately trained nor had sufficient knowledge regarding Essure®; (3) failing to report and actively concealing eight perforations which occurred

as a result of Essure®; (4) erroneously using non-conforming material in the manufacturing of Essure®; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure® at an unlicensed facility; and (7) manufacturing Essure® for three years without license to do so.

232. Defendants failed to adequately train the physicians on how to use their delivery system and the hysteroscopic equipment manufactured by a third party, provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use the same, and created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing and monopolizing the birth control market.

233. Defendants negligently trained physicians, including the Plaintiffs' implanting physicians on how to properly and safely use its hysteroscopic equipment while performing Essure® procedures.

234. The skills needed to place the micro-inserts, as recognized by the FDA panel, "are way beyond the usual gynecologist." Specifically, Dr. Cindy Basinki stated while presenting to the panel, "optimal patient outcomes with either laparoscopic or hysteroscopic permanent contraception is premised on the underlying skills of the physician, and the value of good hysteroscopic skills is an important aspect of the Essure® procedure."[7]

235. A key study found that a learning curve for this hysteroscopic procedure was seen for procedure time, but not for successful placement, pain, and complication rates, evidencing that Defendants' training methods were failing.[8]

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[7] Dr. Cindy Basinki, M.D., FACOG, FPMRS, is a private practitioner, educator and researcher who presented at the FDA's Obstetrics and Gynecology Devices Panel. During her presentation, Dr. Basinki addressed the importance of implanting physicians possessing good hysteroscopic skills when performing the Essure® procedure.

[8] *Learning curve of hysteroscopic placement of tubal serilization micro inserts*, U.S. National Library of Medicine, Janse, JA.

236. Defendants provided hysteroscopic equipment to implanting physicians who were not competently trained to use such a device. Defendants knew the implanting physicians were not competently trained to use such sophisticated equipment but yet provided the equipment to them anyway in order to sell Essure® at a higher volume.

F. WEBSITE WARRANTIES

237. Plaintiffs relied on the following warranties by Defendants and/or its agents, as outlined in the subsequent paragraphs.

238. Defendant Bayer Healthcare Pharmaceuticals, Inc., marketed on its website the following false or misleading representations:

i. "Only FDA approved female sterilization procedure to have **zero pregnancies** in the clinical trials."

- In fact, there were actually **four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience**. Defendants concealed this information from Plaintiffs.

ii. "Physicians must be signed-off to perform Essure® procedures."

- In fact, Defendants failed to adequately train the implanting physicians and "signed-off" on the implanting physicians who did not have the requisite training.[9] Defendants concealed this information from Plaintiffs.

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[9] In fact, during the FDA Panel on Obstetrics and Gynecology Devices, it was suggested that there be "some type of proficiency assessment" for implanting physicians to undergo prior to performing Essure® procedures.

iii. "Surgery-free"

- In fact, Essure® is not "surgery-free". All Essure® procedures are done under hysteroscopy, which is a surgical procedure.

iv. "Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy"

- In fact, **several pregnancies have been reported** subsequent to confirmation. Defendants concealed this information from Plaintiffs.
- Between 1997 and 2005, **64 pregnancies were reported** to Defendants. Defendants concealed this information from Plaintiffs.
- Adverse Event Report ESS 205, dated 10/3/2006, evidences a pregnancy after the three month Confirmation Test was confirmed. Defendants concealed this information from Plaintiffs.
- There have been over **30 pregnancies** after **"doctors confirmed the tubes were blocked."**
- Women who have Essure® have a **10 times greater risk of pregnancy after one year** than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four times greater.[10]

v. "Essure® is the most effective permanent birth control available, even more effective than tying your tubes or a vasectomy."

- In fact, Defendants' SEC filings, Form 10-k, show that no comparison to a vasectomy or tying of tubes was ever done by Defendants. Defendants stated, "We did not conduct a clinical trial to compare the

[10] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.

Essure® procedure to laparoscopic tubal ligation." Defendants concealed this information from Plaintiffs.

- And women who have Essure® have a 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater.[11]

vi. "Correct placement . . . is performed easily because of the design of the micro-insert."

- In fact, Defendants admitted that placement of the device requires a "skilled approach" and even admitted that **their own experts in hysteroscopy** (as compared to general gynecologists not on the same level as an expert hysteroscopist) **failed to place the micro-inserts in 1 out of 7 clinical participants**. Defendants concealed this information from Plaintiffs.

vii. "An Essure® trained doctor inserts spring-like coils, called micro-inserts . . . ;

- In fact, the implanting physicians who implanted the devices were not adequately trained. Defendants concealed this information from Plaintiffs.

viii. "The Essure® training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure® micro-inserts for permanent birth control."

[11] *Id.*

- In fact, Defendants failed to adequately train the implanting physician. Defendants concealed this information from Plaintiffs.

ix. "In order to be trained in Essure® you must be a skilled operative hysteroscopist. You will find the procedures easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure."

- In fact, Defendants "signed off" on implanting physicians who were not skilled operative hysteroscopists in order to capture and monopolize the market, including the implanting physicians. Defendants concealed this information from Plaintiffs.

x. Essure® is a surgery-free permanent birth-control."

- In fact, Essure® is not permanent as the coils can migrate, perforate organs, and be expelled by the body.

G. ADVERTISEMENT WARRANTIES

239. Defendants advertised the following false or misleading representations:

i. "Zero pregnancies" in its clinical trials.

- In fact, there were **at least four pregnancies**. Defendants concealed this information from Plaintiffs.

ii. In order to be identified as a qualified Essure® physician, a minimum of one Essure® procedure must be performed every 6-8 weeks.

- In fact, Defendants **"signed off" on "Essure® physicians" who did not perform the procedure every 6-8 weeks**, including the

implanting physicians. Defendants concealed this information from Plaintiffs.

H. PHYSICIAN TRAINING MANUAL WARRANTIES

240. In their physician training manuals, Defendants stated:

i. "99% of women rated their comfort as good to excellent at all follow-up visits"

- In fact, the actual choices given to the clinical participants were 'poor,' 'very good' or 'excellent.' Defendants concealed this information from Plaintiffs.

I. WARRANTIES BY AGENTS

241. Defendants' Senior Director of Global Professional Education represented to the public:

ii. "For the Essure® procedure, the patient is not under anesthesia, therefore a skilled approach is crucial."

- Yet, Defendants also publicly claim that "[c]orrect placement . . . is performed easily because of the design of the micro-insert."
- In reality, most Essure® devices are placed while the patient is under anesthesia.

242. Defendants' CEO stated:

i. "Essure® allows you to push away the constant worry about an unplanned pregnancy that's our message and that's our theme."

- In fact, there were actually **four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience.** Defendants concealed this information from Plaintiffs.
- From 1997-2005, **64 pregnancies were reported to Defendants.** Defendants concealed this information from Plaintiffs.
- There have been over **30 pregnancies after "doctors confirmed the tubes were blocked."**
- In contrast, Defendants' SEC filings, Form 10-k, show that the HSG test used to confirm the tubes are blocked has been described by Defendants as **"painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."**

J. MARKETING WARRANTIES

243. Defendants marketed with televised commercials containing the following false or misleading representations:

i. Essure® has been in use for over 5 years.

- In fact, Essure® was only in use for 4 years at the time of this. Defendants concealed this information from Plaintiffs.

ii. "The non-surgical permanent birth control for women."

- In fact, the procedure is most commonly done with surgery. Defendants concealed this information from Plaintiffs.
- Essure® is not permanent because the coils can migrate, perforate organs, and be expelled by the body.

- And all Essure® procedures are done under hysteroscopy, which is a surgical procedure.

iii. "Essure® allows for visual confirmation of each insert's proper placement both during the procedure and during the Essure® Confirmation Test."

- In fact, Essure® does not allow for visual confirmation of proper placement during the procedure.

K. BROCHURE WARRANTIES

244. Defendants' Essure® brochure included the following false or misleading representations and warranties:

i. Essure® is "worry free."

- Defendants actively concealed and **failed to report 8 perforations** which occurred as a result of Essure® to the FDA as evidenced in a Form 483 issued by the FDA to Defendants. Defendants actively concealed this from Plaintiffs.
- Defendants failed to notify the FDA of their internal records of **16,047 complaints** regarding Essure.
- Defendants' SEC filings, Form 10-K, show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "**painful and is also known to be highly inaccurate, with false-positive results in as many as 40%.**"
- Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations, and instances where Essure® broke into pieces; were cited for having an incomplete risk analysis, not

documenting non-conforming products, not following procedures used to control non-conforming products, and other quality problems.

ii. "The Essure® inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

- In fact, the micro-inserts do not remain secure but can migrate and be expelled by the body. Defendants actively concealed this information from Plaintiffs.
- Defendants actively concealed and **failed to report 8 perforations** which occurred as a result of Essure® to the FDA as evidenced in Form 483 issued to Defendants by the FDA.
- Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations, and instances where Essure® broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-conforming product, and other quality problems.

iii. "The Essure® inserts are made from the same trusted, silicone free material used in heart stents."

- In fact, the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiffs.

- PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion.
- PET fibers are not designed or manufactured for use in human implantation.
- Additionally, Defendants were fully aware that "the long-term nature of the tissue response to the Essure® micro-insert is not known."
- Defendants were issued another Form 483 when they "**erroneously used non-conforming material**." Defendants actively concealed this and were issued another Form 483 for "failing to adequately document the situation."

iv. Essure® is "surgery free":

- In fact, all Essure® procedures are done under hysteroscopy, which is a surgical procedure.

v. Essure® is "Anesthesia-free"

- In fact, Essure® is not "anesthesia-free;" rather anesthesia is not always required.
- Most women are administered anesthesia prior to placement of the Essure® devices.

vi. Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

- In contrast, Defendants also state that it is only after "The Confirmation" that pregnancy cannot occur, which is inconsistent with what Defendants warranted in their brochure.

- Adverse Event Report ESS 205, dated 10/3/2006, evidences a pregnancy after the three month confirmation test was confirmed.
- Between 1997 and 2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiffs.
- There have been over 30 pregnancies after **"doctors confirmed the tubes were blocked."**
- There have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test, thereby making pregnancy possible.

vii. "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures."

- In fact, Essure® is not "surgery-free", rather surgery is not required.
- Defendants' SEC filings, Form 10-K, show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "**painful and is also known to be highly inaccurate, with false-positive results in as many as 40%.**"

viii. The PET fibers are what causes the tissue growth

- In contrast, Defendants represented to the FDA at the PMA meeting that the trauma caused by the expanding coil striking the fallopian tubes is what causes the inflammatory response of the tissue. Defendants concealed this information from Plaintiffs.

ix. "The inserts are made from . . . safe, trusted material."

- In fact, the inserts are not made of safe, trusted material as they migrate, break, and contain drugs. In fact, Defendants refer to Essure® and classify it as a "drug."

x. In January 2014, Defendants represented that over 750,000 procedures had been performed.

- Ten months later, Defendants admitted that only 625,000 procedures had actually been performed.

L. PATIENT INFORMATION BOOKLET WARRANTIES

245. Defendants' Patient Information Booklet includes the following representations:

i. "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

- However, the device does irritate the uterus and, in some cases, has even become embedded within patients' uteruses. Defendants concealed this information from Plaintiffs.
- Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure® to the FDA as evidenced in Form 483.
- Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations, and instances where Essure® broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming product, and other quality problems.

ii. "there was no cutting, no pain, no scars . . ."

- Plaintiffs have experienced pain as a result of Essure. Defendants concealed this information from Plaintiffs.
- Defendants' SEC filings, Form 10-K, show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."
- Defendants were issued Form 483's for not disclosing MDR's to the FDA for pain.

M. SUMMARY OF SAFETY AND EFFECTIVENESS DATA

246. Summary of Safety and Effectiveness Data per information provided by Defendants to the FDA states:

i. "The Essure® System provides permanent birth control without invasive surgery or general anesthesia, and their associated risks."
   - Essure® is not "surgery-free" or "anesthesia-free," rather surgery and anesthesia are not required.

ii. "In addition to the above benefits, none of the women in the Essure® clinical trials became pregnant while relying on Essure® for contraception."
   - In fact, there were at least four pregnancies during the clinical trials. Defendants concealed this information from Plaintiffs.

iii. "Namely, the Essure® system is delivered hysteroscopically without general anesthesia."
   - Essure® is not "surgery-free" or "anesthesia-free," rather surgery and anesthesia is not required.

N. PMA SUPPLEMENT

247. Defendants represented to Plaintiffs that it was the expanding coil and tissue growth that caused the coil to become attached to the fallopian tubes—not any type of coating.

248. However, in PMA Supplement 18, Defendants represented that "A doctor placed the coil at the uterine-fallopian tube junction, where its coating caused it to be attached to the tube." The coating is a hydrophilic polymer coating produced at AST Products, Inc. Defendants actively concealed this from Plaintiffs.

O. SEC FILINGS

249. In an SEC Form 10-K filing on March 15, 2011, Defendants made the following representation:

i. "Our Mountain View, California facility underwent an International Organization for Standardization ("ISO") inspection in August 2010 which resulted in continuing approval and ISO certification through May of 2013. In December 2010 / January 2011 we underwent an FDA audit; all findings from the audit were satisfactorily addressed."

- In fact, Defendants' manufacturing facility has been inspected 7 times since July 9, 2002. The most recent FDA audit occurred from May 30 through June 26, 2013. The FDA has issued 4 Form 483 inspectional observations.
- However, Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure® to the FDA as evidenced in Form 483.

- Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this. Further, Defendants were issued another Form 483 for "failing to adequately document the situation."
- Defendants' facility was also issued a violation as it "no longer uses pre-sterile and post-sterile cages."
- Defendants were also issued a violation when they "failed to obtain a valid license . . . prior to manufacturing medical devices." Defendants were manufacturing devices for three years without a license.
- Defendants failed to inform the FDA and Plaintiffs of their internal records of 16,047 complaints.
- Defendants were issued Form 483s for not disclosing MDR's to the FDA for perforations, migrations, and instances where Essure® broke into pieces; were cited for having an incomplete risk analysis, not documenting non-confirming products, not following procedures used to control non-conforming product, and other quality problems.

P. ADDITIONAL FDA ACTION IN 2016

250. On February 29, 2016, the FDA announced actions to provide important information about the risks of using Essure® and to help women and their doctors be better informed of the potential complications associated with implantable forms of sterilization. The FDA issued a new, mandatory clinical study for Essure® to determine heightened risks for particular women. The FDA also intends to require changes to product labeling, including a boxed warning and a Patient Decision Checklist to help ensure that women receive and

understand information regarding the benefits and risks of this type of device. The FDA has issued a draft guidance to provide the public an opportunity to comment on the proposed language to be included in these warnings.

251. As the FDA stated in its News Release issued on February 29, 2016, "[w]hile the FDA believes Essure® remains an appropriate option for the majority of women seeking a permanent form of birth control, some women may be at risk for serious complications . . . [including] persistent pain, perforation of the uterus or fallopian tubes from device migration, abnormal bleeding and allergy or hypersensitivity reactions."

252. Moreover, William Maisel, M.D., M.P.H., deputy director for science and chief scientist at the FDA's Center for Devices and Radiological Health, acknowledged that the FDA's actions "also reflect [FDA's] recognition that more rigorous research is needed to better understand if certain women are at heightened risk of complications."

253. On March 4, 2016, the FDA released a draft guidance to provide the public an opportunity to comment on the proposed language to be included in the warning label for Essure®. Accordingly, the FDA proposed the following black box warning for such devices:

> **WARNING: Some patients implanted with the Essure® System for Permanent Birth Control have reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions. Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device.**

254. Additionally, the FDA proposed a patient decision checklist containing the following excerpts:

"I understand that if I experience any of the following, I should contact my physician:

- Abdominal, pelvic or back pain that develops or persists more than 1 week following insertion. Data suggest that for those women who do experience pain during and/or immediately after the procedure, most will have their symptoms resolve within a few days, and 99% will have their symptoms resolve within 1 week.
- Signs or symptoms consistent with an allergic or hypersensitivity reaction. These may include persistent changes in my skin (rash, itching) but may also include other persistent symptoms such as chest pain, palpitations, breathing difficulties or wheezing, and intestinal discomfort such as nausea, diarrhea, and vomiting. These types of events, although not reported in the clinical trials supporting device approval, have been reported by women implanted with the Essure® System.
- Other signs or symptoms that continue or recur including joint or muscle pain, muscle weakness, excessive fatigue, hair loss, weight changes, and mood changes. These types of events, although not reported in the clinical trials supporting device approval, have been reported to the FDA by women implanted with the Essure® System."

Q. E-FREE ACT

255. In November 2015, Representative Michael Fitzpatrick of the 8th District of Pennsylvania introduced the E-Free Act, H.R. 3920, which requires the FDA to withdraw its approval for Essure®.

256. Further, on February 17, 2016, Representative Fitzpatrick also drafted a letter to Jeffrey Shuren, the Director of the Center for Devices and Radiological Health. In this letter, Representative Fitzpatrick reported that Essure® has tragically "killed innocent women and unborn children." Further, Representative Fitzpatrick noted that while the "FDA's public materials related to Essure® have cited five reports of fetal deaths," his office was in receipt of an independent report counting 303 fetal deaths.

257. Defendants actively concealed the information pertaining to their numerous violations. In doing so, Defendants never disclosed this information to Plaintiffs. In fact, had Plaintiffs known that Defendants were concealing thousands of complaints of adverse reactions to Essure®, using non-conforming materials not approved by the FDA in manufacturing Essure®, not using sterile cages in manufacturing Essure®, and using an unlicensed manufacturing facility to manufacture Essure®, Plaintiffs would not have had Essure® implanted.

258. Accordingly, Plaintiffs would not have sustained the serious personal injuries they did after being implanted with Essure® but for Defendants' wrongful conduct alleged herein.

VI

CAUSES OF ACTION

FIRST CAUSE OF ACTION
(Breach of Express Warranty)

259. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth at length herein.

260. Under Pennsylvania law, state and federal courts alike have held that claims for breach of express warranties are not preempted by the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug and Cosmetic Act of 1938. *Rosci v. Acromed, Inc.*, 447 Pa.Super.403 (Pa. Super. Ct. 1995); *Bentzley v. Medtronic, Inc.*, 827 F.Supp.2d 443, 454-55 (E.D. Pa. 2011).

261. In fact, the FDA expressly stated in its CPMA notice to Defendants the following: "CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

262. Plaintiffs' claims arise out of injuries caused by Defendants' express warranties

made explicitly to Plaintiffs and their physicians as to the safety and effectiveness of the Essure® device.

263. Plaintiffs relied on Defendants' express warranties as to the safety and effectiveness of the Essure® to their detriment.

264. Defendants intentionally made the following statements in the brochures they distributed to physicians to make available to patients in order to induce Plaintiffs to undergo the Essure® procedure as opposed to using other forms of birth control:

i. Essure® is "worry free."

ii. "The Essure® inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

iii. "The Essure® inserts are made from the same trusted, silicone free material used in heart stents."

iv. Essure® is "surgery free."

v. Essure® is "Anesthesia-free."

vi. Step Two: "pregnancy cannot occur."

vii. Step Three: "The Confirmation."

viii. "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures."

265. Defendants' "affirmations of fact or promise" and "descriptions" as to the safety and effectiveness of the Essure® devices created the basis of the bargain with Plaintiffs.

266. At all times relevant herein, Defendants' express warranties as to the safety and effectiveness of Essure® were expressly communicated to Plaintiffs and their respective

physicians through the aforementioned Essure® brochures, advertisements, physician training manuals, and other promotional materials (i.e., promotional videos, etc.). As such, Plaintiffs understood and accepted Defendants' express warranties as the basis of their bargain with Defendants in undergoing the implantation of the Essure® device.

267. As a result of Defendants' breach of their express warranties, whether breached individually, jointly, and/or severally, Plaintiffs sustained the following injuries: ectopic pregnancy, unexpected actual pregnancy, medication-induced miscarriages, dysfunctional uterine bleeding, severe blood clotting, complex ovarian cysts, uterine fibroids, rheumatoid arthritis, severe abdominal and menstrual pain, severe back pain, weight fluctuation, migraines, rashes, boils, pain during intercourse, and irregular menstrual periods.

268. As a result of Defendants' breach, individually, jointly, and severally, Plaintiffs had to undergo additional surgical procedures, including: surgical tubal ligation, cystectomy, hysterectomy, endometrial ablation, and dilation and curettage.

269. Further, some Plaintiffs may have to undergo further surgeries, diagnostic testing, treatment, and rehabilitation into the indefinite future.

270. As a result of Defendants' breach of their express warranties, whether breached individually, jointly, and/or severally, Plaintiffs sustained significant pain and suffering, both physical and mental, and which will continue into the indefinite future.

271. As a result of Defendants' breach of their express warranties, whether breached individually, jointly, and/or severally, Plaintiffs have been prescribed a variety of heavy-duty pain medications to treat the injuries they sustained as a result of undergoing implantation of Essure, including: Norco, Percocet, Lyrica, and Vicodin.

272. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies along with related expenses, all to their significant financial detriment and loss, and for which they may have to endure significant financial expenditures into the foreseeable future.

273. As such, Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

SECOND CAUSE OF ACTION
(Fraudulent Misrepresentation)

274. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth at length herein.

275. On information and belief, Plaintiffs allege that Defendants fraudulently misrepresented the safety and effectiveness of Essure® as specifically detailed above.

276. Under Pennsylvania law, fraud may be established even where a misrepresentation is made innocently so long as the misrepresentation relates to a matter material to the case. As such, pleading the materiality of the misrepresentation substitutes for pleading the fraudulent misrepresentation.

277. Alternatively, the facts misrepresented by Defendants in this case were certainly material to Plaintiffs as they would not have undergone implantation of Essure® had they been aware of Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

278. Accordingly, Defendants intentionally made the following statements in the brochures they distributed to physicians to make available to patients in order to induce Plaintiffs to undergo the Essure® procedure instead of using other forms of birth control:

i. Essure® is "worry free."

ii. "The Essure® inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

iii. "The Essure® inserts are made from the same trusted, silicone free material used in heart stents."

iv. Essure® is "surgery free."

v. Essure® is "Anesthesia-free."

vi. Step Two: "pregnancy cannot occur."

vii. Step Three: "The Confirmation."

viii. "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures."

279. Plaintiffs justifiably relied on these misrepresentations and would not have undergone implantation of Essure® had they been aware of the falsity of Defendants' representations as set forth above and which violated both federal law and the CPMA.

280. As a result of Plaintiffs' justifiable reliance on Defendants' fraudulent misrepresentations, whether individually, jointly, and/or severally made, Plaintiffs sustained the following injuries: ectopic pregnancy, unexpected actual pregnancy, medication-induced miscarriages, dysfunctional uterine bleeding, severe blood clotting, complex ovarian cysts, uterine fibroids, rheumatoid arthritis, severe abdominal and menstrual pain, severe back pain, weight fluctuation, migraines, rashes, boils, pain during intercourse, and irregular menstrual periods.

281. As a result of Plaintiffs' justifiable reliance on Defendants' fraudulent misrepresentations, whether individually, jointly, and/or severally made, some Plaintiffs have

had to undergo additional surgical procedures, including: surgical tubal ligation, cystectomy, hysterectomy, endometrial ablation, and dilation and curettage. Further, some Plaintiffs may have to undergo further surgeries, diagnostic testing, treatment, and rehabilitation into the indefinite future.

282. As a result of Plaintiffs' justifiable reliance on Defendants' fraudulent misrepresentations, whether individually, jointly, and/or severally made, Plaintiffs sustained significant pain and suffering, both physical and mental, which will continue into the indefinite future.

283. As a result of Plaintiffs' justifiable reliance on Defendants' fraudulent misrepresentations, whether individually, jointly, and/or severally made, Plaintiffs have been prescribed a variety of heavy-duty pain medications to treat the injuries they sustained as a result of undergoing implantation of Essure, including: Norco, Percocet, Lyrica and Vicodin.

284. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies along with related expenses, all to their significant financial detriment and loss, and for which they may have to endure significant financial expenditures into the foreseeable future.

285. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

THIRD CAUSE OF ACTION
(Negligent Misrepresentation)

286. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth at length herein.

287. On information and belief, Plaintiffs allege Defendants negligently misrepresented several facts relating to the safety and effectiveness of Essure® as fully alleged

above in the section entitled "Facts and Warranties" and including the following.

288. As a result of Plaintiffs' justifiable reliance on Defendants' negligent misrepresentations, whether individually, jointly, and/or severally made, Plaintiffs sustained the following injuries: ectopic pregnancy, unexpected actual pregnancy, medication-induced miscarriages, dysfunctional uterine bleeding, severe blood clotting, complex ovarian cysts, uterine fibroids, rheumatoid arthritis, severe abdominal and menstrual pain, severe back pain, weight fluctuation, migraines, rashes, boils, pain during intercourse, and irregular menstrual periods.

289. As a result of Plaintiffs' justifiable reliance on Defendants' negligent misrepresentations, whether individually, jointly, and/or severally made, some Plaintiffs have had to undergo additional surgical procedures, including: surgical tubal ligation, cystectomy, hysterectomy, endometrial ablation, and dilation and curettage. Further, some Plaintiffs may have to undergo further surgeries, diagnostic testing, treatment, and rehabilitation into the indefinite future.

290. As a result of Plaintiffs' justifiable reliance on Defendants' negligent misrepresentations, whether individually, jointly, and/or severally made, Plaintiffs sustained significant pain and suffering, both physical and mental, which will continue into the indefinite future.

291. As a result of Plaintiffs' justifiable reliance on Defendants' negligent misrepresentations, whether individually, jointly, and/or severally made, Plaintiffs have been prescribed a variety of heavy-duty pain medications to treat the injuries they sustained as a result of undergoing implantation of Essure, including: Norco, Percocet, Lyrica and Vicodin.

292. Accordingly, Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies along with related expenses, all to their significant financial detriment and loss, and for which they may have to endure significant financial expenditures into the foreseeable future.

293. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

FOURTH CAUSE OF ACTION
(Negligent Failure to Warn)

294. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth at length herein.

295. Plaintiffs' injuries were caused by Defendants' negligent and reckless conduct in failing to warn Plaintiffs or their implanting physicians. In doing so, Defendants committed the following violations of federal law and its CPMA:

296. Defendants had a duty to warn Plaintiffs and/or their implanting physicians consistent with federal law and the CPMA and included:

i. 21 C.F.R. 814, governing premarket approval of medical devices, a *Statement of material fact* means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or **silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact,** even if the statement was not intended by the person making it to be misleading or to have any probative effect.

ii. 21 C.F.R. 814.80—A device **may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval** specified in the PMA approval order for the device.

iii. 21 C.F.R. 820.65—establish and **maintain procedures for identifying with a control number each unit, lot, or batch of finished devices** and where appropriate components. The procedures shall facilitate corrective action.

iv. 21 C.F.R. 803.1(a)—This part establishes **the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files.** If you are a manufacturer, you must also submit specified follow-up. **These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.**

v. 21 C.F.R. 803.10—(a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event :(i) Submit reports of device related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us. (2) Submit annual reports (described in 803.33) to us. (b) If you are an importer, you must submit reports (described in subpart D of this part), as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or (ii) Submit reports of device-related malfunctions to the manufacturer. (2) [Reserved] (c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction. (2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of: (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or (ii) A reportable event for which we made a written request. (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

vi. 21 C.F.R. 803.50(a)—(a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:(1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. (b) What information does FDA consider "reasonably known" to me? (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the

following information to be reasonably known to you: (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device. (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.(3) **You are also responsible for conducting an investigation of each event and evaluating the cause of the event.** If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

vii. 21 C.F.R. 803.53—**You must submit a 5-day report** to us, on Form 3500A or an electronic equivalent approved under 803.14, **no later than 5 work days after the day that you become aware that:(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.** You may become aware of the need for remedial action from any information, including any trend analysis; or (b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

viii. 21 C.F.R. 806.10—(a) **Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device; or (2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b). (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days** of initiating such correction or removal…

ix. 21 C.F.R. 814.84—(a) **The holder of an approved PMA shall** comply with the requirements of part 803 **and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device.** (b) Unless FDA specifies otherwise, **any periodic report shall:** (1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b). **(2) Contain a summary and bibliography of the following information not previously submitted as part of the**

PMA: (I) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant. (ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted. (3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter. (4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

x. 21 C.F.R. 820.65—**Each manufacturer of a device that is intended for surgical implant into the body** or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user **shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.** Such identification shall be documented in the DHR.

xi. 21 C.F.R. 822—Post market surveillance—This part **implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of class II and class III devices** that meet any of the following criteria: (a) Failure of the device would be reasonably likely to have serious adverse health consequences; (b) **The device is intended to be implanted in the human body for more than 1 year;**... The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

xii. (l) 21 C.F.R. 820.100(a)—6 -7- Corrective and Preventive Action-(a) Each manufacturer **shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.** Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems; (2) Investigating the cause of nonconformities relating to product, processes, and the quality system; (3)

Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review. (b) All activities required under this section, and their results, shall be documented.

xiii. 21 C.F.R. 820.70(e)(h)—(a) *General.* **Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include: (1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;** (2) Monitoring and control of process parameters and component and device characteristics during production; (3) Compliance with specified reference standards or codes; (4) The approval of processes and process equipment; and (5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples. (b) *Production and process changes.* Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40. (e) ***Contamination control.*** **Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.** (h) *Manufacturing material.* **Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.**

xiv. 21 C.F.R. 820.90—(a) ***Control of nonconforming product.*** Each manufacturer **shall establish and maintain procedures to control product that does not conform to specified requirements.** The procedures shall

address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. **The evaluation and any investigation shall be documented.** (b) *Nonconformity review and disposition.* (1) **Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented.** Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use. (2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

xv. 21 C.F.R. 820.90—(a) Each manufacturer **shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination,** or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate. (b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

xvi. 21 C.F.R. 820.180—**All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available** for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

xvii. 21 C.F.R. 820.198—(a) **Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA**

under part 803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) **Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.** (d) **Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified.** In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include: (1) The name of the device; (2) The date the complaint was received;(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; (4) The name, address, and phone number of the complainant; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action taken; and (8) Any reply to the complainant. (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor.

xviii. 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a)—**A drug or device shall be deemed to be misbranded…If its labeling is false or misleading. The following acts and the causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce…any device that is adulterated or misbranded.**

xix. 21 U.S.C. 351(a) (h)—**A drug or device shall deemed to be adulterated**…if it has been prepared, packed, or held under insanitary conditions whereby it **may have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with**

current good manufacturing practice…is…not in conformity with …an applicable condition prescribed by an order.

xx. 21 U.S.C. 352 (q) (r)—Restricted devices using false or misleading advertising or used in violation of regulations. **In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular,** or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title. **Restricted devices not carrying requisite accompanying statements in advertisements** and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes **in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer,** packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

xxi. FDA requirement in CPMA order—**"Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."**

xxii. FDA requirement in CPMA order—**"Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests** that the device may have caused or contributed to a serious injury."

xxiii. FDA requirement in CPMA order—Report Due Dates- six month, one year, eighteenth month, and two year reports. (y) FDA requirement in CPMA order - **A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.**

xxiv. FDA requirement in CPMA order—Warranties are truthful, accurate, and not misleading. . . . Warranties are consistent with applicable Federal and State law.

297. Defendants breached these duties by not complying with its CPMA or Federal law:

i. Defendants failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteen month and two year reports. All reports failed to meet the respective deadlines.

ii. Defendants failed to document successful placement of Essure® concealing the failure rates.

iii. Defendants failed to notice the FDA of several adverse reactions and actively concealed the same. Defendants failed to report 8 perforations which occurred as a result of Essure® and was cited for the same by the FDA via Form 483.[12]

iv. Defendants failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury concealing the injuries. Again, Defendants failed to report 8 perforations as adverse events which occurred as a result of Essure® to the FDA as evidenced in Form 483.

v. Defendants failed to notice the FDA of their internal records containing 16,047 complaints.

[12] Form 483 is issued to firm management at the conclusion of inspection when an FDA investigator has observed any conditions that violate the FDCA rendering the device "adulterated."

vi. Defendants excluded the risk assessment for safety of loose coils in its Risk Management Plan and stated that Defendants had not violated the FDCA.

vii. Defendants erroneously **used non-conforming material** in the manufacturing of Essure.

viii. Defendants failed to use **pre-sterile and post-sterile cages.**

ix. Defendants manufactured Essure® **at an unlicensed facility.**

x. Defendants manufactured Essure® for three years **without a license to do so.**

xi. Defendants failed to report complaints in which their product migrated.

xii. Defendants failed to consider these complaints in their risk analysis for the design of Essure®.

xiii. On January 6, 2011, the FDA issued a violation to Defendants for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." These failures included incidents regarding perforation of bowels, Essure® coils breaking into pieces, and Essure® coils migrating out of the fallopian tubes. Defendants were issued these violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.

xiv. Defendants had notice of **168 perforations but only disclosed 22 to the FDA.**

xv. On January 6, 2011, Defendants were cited for having an incomplete risk analysis of Essure®. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure® did not include the location of the micro-insert coil in the peritoneal cavity as a potential failure mode or effect.

xvi. On January 6, 2011, Defendants were cited for failing to document Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' design.

xvii. On July 7, 2003, Defendants were cited for not identifying existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).

xviii. On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

xix. Defendants failed to disclose to Plaintiffs and their respective implanting physicians the fact that Defendants altered medical records to reflect less pain then was being reported during the clinical studies for Essure® and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.

298. Had Defendants disclosed such information as they were required to pursuant to the CPMA and federal law to Plaintiffs or their respective implanting physicians, Plaintiffs would not have had the Essure® device implanted.

299. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained the following injuries all of which could be permanent in nature: ectopic pregnancy, unexpected actual pregnancy, medication-induced miscarriages, dysfunctional uterine bleeding, severe blood clotting, complex ovarian cysts, uterine fibroids, rheumatoid arthritis, severe abdominal and menstrual pain, severe back pain, weight fluctuation, migraines, rashes, boils, pain during intercourse, and irregular menstrual periods.

300. As a result of Defendants' negligence, individually, jointly, and/or severally, some Plaintiffs have had to undergo additional surgical procedures, including: surgical tubal ligation, cystectomy, hysterectomy, endometrial ablation, and dilation and curettage. Some Plaintiffs may have to undergo further surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

301. As a result of Defendants' negligence, individually, jointly, and/or severally, Plaintiffs sustained significant pain and suffering, both physical and mental, which will continue into the indefinite future.

302. As a result of Defendants' negligence, individually, jointly, and/or severally, Plaintiffs have been prescribed a variety of heavy-duty pain medications to treat the injuries they sustained as a result of undergoing implantation of Essure®, including: Norco, Percocet, Lyrica and Vicodin.

303. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies along with related expenses, all to

their significant financial detriment and loss, for which they may have to endure significant financial expenditures into the foreseeable future.

304. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

FIFTH CAUSE OF ACTION
(Negligent Training)

305. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth at length herein.

306. Defendants undertook an independent duty to train physicians on how to properly use the device necessary to properly place the Essure® micro-inserts. However, in doing so, Defendants failed to follow the FDA's training guidelines.

307. In voluntarily undertaking a duty to train physicians Defendants created an "Essure Training Program," created a simulation program call EssureSim, organized limited training courses, where Defendants observed physicians until Defendants believed they were competent to perform the Essure® procedure, created the Essure® Procedure Equipment Supplies Checklist, and represented to Plaintiffs that "Physicians must be signed-off to perform Essure® procedures."

308. By creating this training program, Defendants had a duty to abide by the FDA training guidelines for how to train implanting physicians on how to properly place Essure® using its own delivery system. Additionally, Defendants had a duty to disclose adverse events to the physicians so that they could then properly advise their patients of the actual risks involved with undergoing the Essure® procedure.

309. As such, pursuant to FDA-approved training regulations and guidelines, Defendants had a duty to comply with the following Federal requirements so that implanting

physicians were capable of performing "competent procedures" and able to "manage possible technical issues," including the following:

i. Ensuring that the implanting physicians completed the required preceptoring (generally 5 Essure® procedures) in Essure® placement until he or she was competent;

ii. Ensuring that the implanting physicians had read and understood the Physician Training Manual;

iii. Ensuring that the implanting physicians monitored Plaintiffs through recovery;

iv. Ensuring that the implanting physicians were knowledgeable hysteroscopists (prior to Essure® training);

v. Ensuring that the implanting physicians were certified under the aforementioned requirements.

310. As set forth in the Physicians Manual these requirements were necessary for:

i. Ensuring that the implanting physicians were selecting appropriate patients to perform the Essure® procedure on;

ii. Ensuring that the implanting physicians were appropriately counseling Plaintiffs on the known risks associated with Essure®; and

iii. Ensuring the implanting physician was qualified and competent to perform the Essure® procedure to ensure proper placement to preclude migration, perforation and fracturing of coils.

311. In negligently training the implanting physicians in this case, Defendants breached this duty under Pennsylvania law and as such, departed from the FDA-approved training guidelines by:

i. Failing to ensure that the implanting physicians completed the required preceptoring in performing Essure® procedures until they reached competency. However, the implanting physicians did not complete the required preceptoring, which would have been five successful Essure® procedures.

ii. Failing to ensure that the implanting physicians read and understood the Physician Training Manual in its entirety. Here, the implanting physicians did not understand the Physician Training Manual.

iii. Failing to ensure that the implanting physicians monitored Plaintiffs through recovery. Here, the implanting physicians did not so monitor Plaintiffs through their respective recoveries.

iv. Failing to ensure that the implanting physicians were knowledgeable hysteroscopists (prior to participating in the Essure® training program). Here, the implanting physicians were not knowledgeable hysteroscopists prior to participating in the Essure® physician training program.

v. Failing to ensure that the implanting physicians were certified under the preceding requirements. Here, the implanting physicians were not certified under Defendants' requirements.

312. Defendants' departure from the training guidelines caused Plaintiffs' Essure® devices to migrate from their fallopian tubes, perforate, and/or caused Plaintiffs to suffer the following injuries: ectopic pregnancy, unexpected actual pregnancy, medication-induced miscarriages, dysfunctional uterine bleeding, severe blood clotting, complex ovarian cysts, uterine fibroids, rheumatoid arthritis, severe abdominal and menstrual pain, severe back pain, weight fluctuation, migraines, rashes, boils, pain during intercourse, and irregular menstrual periods. These injuries were caused by Defendants' negligent training of the implanting physicians in the following ways:

i. The Essure® Training Program ensured that the implanting physicians were adequately trained in proper placement of Essure®. However, without adequate training in this regard, implanting physicians' technique caused the coils to migrate, perforate, and/or fracture thus, resulting in Plaintiffs' injuries.

ii. The required preceptoring ensured that the implanting physicians were adequately trained in proper placement of Essure®. However, without adequate training in this regard, implanting physicians' technique caused the coils to migrate, perforate, and/or fracture, thus resulting in Plaintiffs' injuries.

iii. The requirement that the implanting physicians read and understood the Physician Training Manual ensured that implanting physicians were adequately trained in proper placement of Essure®. However, without ensuring that they read and understood the Physician Training Manual, the implanting physicians' technique caused the coils to migrate, perforate, and/or fracture thus, resulting in Plaintiffs' injuries.

iv. The required monitoring ensured that the implanting physicians were adequately trained in proper placement of Essure®. However, without adequate training in this regard, implanting physicians' technique caused the coils to migrate, perforate, and/or fracture, thus resulting in Plaintiffs' injuries.

v. The requirement that the implanting physicians be knowledgeable hysteroscopists ensured that Plaintiffs' Essure® devices were properly placed. However, the fact that the implanting physicians were not knowledgeable hysteroscopists caused the coils to migrate, perforate, and/or fracture, thus resulting in Plaintiffs' injuries.

vi. The requirement that the implanting physicians be certified under the requirements set forth above ensured that Plaintiffs' Essure® devices were properly placed. However, the fact that the implanting physicians were not certified in this regard caused the coils to migrate, perforate, and/or fracture, thus resulting in Plaintiffs' injuries.

313. As a result of Defendants' negligent training of the implanting physicians, Plaintiffs sustained the following injuries all of which could be permanent in nature: ectopic pregnancy, unexpected actual pregnancy, medication-induced miscarriages, dysfunctional uterine bleeding, severe blood clotting, complex ovarian cysts, uterine fibroids, rheumatoid arthritis, severe abdominal and menstrual pain, severe back pain, weight fluctuation, migraines, rashes, boils, pain during intercourse, and irregular menstrual periods.

314. As a result of Defendants' negligence, individually, jointly, and/or severally, some Plaintiffs have had to undergo additional surgical procedures, including: surgical tubal ligation, cystectomy, hysterectomy, endometrial ablation, and dilation and curettage. Some Plaintiffs may have to undergo further surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

315. As a result of Defendants' negligence, individually, jointly, and/or severally, Plaintiffs sustained significant pain and suffering, both physical and mental, which will continue into the indefinite future.

316. As a result of Defendants' negligence, individually, jointly, and/or severally, Plaintiffs have been prescribed a variety of heavy-duty pain medications to treat the injuries they sustained as a result of undergoing implantation of Essure®, including: Norco, Percocet, Lyrica and Vicodin.

317. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies along with related expenses, all to their significant financial detriment and loss, for which they may have to endure significant financial expenditures into the foreseeable future.

318. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

SIXTH CAUSE OF ACTION
(Negligence-Manufacturing)

319. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth at length herein

320. Defendants' negligence in manufacturing Essure® in violation of the CPMA and Federal law not only caused Essure® to be what is known as an "adulterated" and "misbranded" product but it has also caused Plaintiffs' injuries in this case.

321. As such, Defendants violated their duty to manufacture Essure® consistent with the following regulations. In doing so, Defendants breached their duties to Plaintiffs by violating the following:

i. The FDA's requirements as set forth in the CPMA order – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

a. In manufacturing Plaintiffs' Essure® devices using non-conforming product and rejected materials, Defendants violated this requirement as set forth in the CPMA. Moreover, Defendants failed to document this violation on its quality assurance form.

ii. 21 C.F.R. 820.65 – Each manufacturer of a device… "shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action."

a. Defendants violated this regulation by manufacturing Essure® by using non-conforming or rejected materials and failing to document its use of such.

iii. 21 C.F.R. 820.70 – (a) Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

a. Defendants violated this regulation by manufacturing Essure® by using non-conforming or rejected materials and failing to document its use of such.

iv. 21 C.F.R. 820.70(e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

a. Defendants violated this regulation by manufacturing Essure® by using non-conforming or rejected materials and failing to document its use of such.

v. 21 C.F.R. 820.70(h) *Manufacturing material.* Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

a. Defendants violated this regulation by manufacturing Essure® by using non-conforming or rejected materials and failing to document its use of such.

vi. 21 C.F.R. 820.90 (a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance.

a. Defendants violated this regulation by manufacturing Essure® by using non-conforming or rejected materials and failing to document its use of such.

vii. 21 U.S.C. 351(h) – a device shall be deemed adulterated if. . .the methods used in, or the facilities or controls used for, its manufacture, packing, storage or installation are not in conformity with applicable requirements…

a. Defendants violated this requirement by manufacturing Essure® in unsanitary conditions and failing to manufacture Essure® in conformance with conditions set forth in the CPMA order. Moreover, Defendants violated this regulation by manufacturing Essure® by using non-conforming or rejected materials and failing to document its use of such.

322. Accordingly, Defendants' breaches, as stated above, caused Plaintiffs' injuries as a result of using nonconforming and rejected materials in Plaintiffs' Essure® devices. As such, Plaintiffs' Essure® devices did not function as intended and Plaintiffs have sustained the following injuries all of which could be permanent in nature: ectopic pregnancy, unexpected actual pregnancy, medication-induced miscarriages, dysfunctional uterine bleeding, severe blood clotting, complex ovarian cysts, uterine fibroids, rheumatoid arthritis, severe abdominal and menstrual pain, severe back pain, weight fluctuation, migraines, rashes, boils, pain during intercourse, and irregular menstrual periods.

323. As a result of Defendants' negligent manufacture of Essure, some Plaintiffs have had to undergo additional surgical procedures, including: surgical tubal ligation, cystectomy, hysterectomy, endometrial ablation, and dilation and curettage. Some Plaintiffs may have to undergo further surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

324. As a result of Defendants' negligence, individually, jointly, and/or severally, Plaintiffs sustained significant pain and suffering, both physical and mental, which will continue into the indefinite future.

325. As a result of Defendants' negligence, individually, jointly, and/or severally, Plaintiffs have been prescribed a variety of heavy-duty pain medications to treat the injuries they sustained as a result of undergoing implantation of Essure®, including: Norco, Percocet, Lyrica and Vicodin.

326. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies along with related expenses, all to their significant financial detriment and loss, for which they may have to endure significant financial expenditures into the foreseeable future.

327. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

SEVENTH CAUSE OF ACTION
(Loss of Consortium as to Plaintiff Jason Long)

328. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth at length herein.

329. In or around September 2013, Plaintiff Crystal Goodwin underwent the Essure® procedure. As a result of undergoing the implantation of Essure®, Plaintiff Long's wife Crystal Goodwin, was subsequently injured as a result of being implanted with Essure®.

330. As a direct and proximate cause of Defendants' conduct, as described above, Plaintiff's wife Crystal Goodwin, continues to suffer from the injuries as set forth previously in this Complaint.

331. Before suffering these injuries, Plaintiff Long's spouse was able to and did perform all the duties of a wife, including providing society and services, such as intimacy, companionship, affection, assistance, and support. Plaintiff Long and his wife had a happy and healthy marital relationship in that they got along well, rarely bickered, worked as a team unit and enjoyed a healthy sexual relationship. Further, prior to undergoing the implantation of Essure®, Plaintiff Long's wife was an active wife and mother, as she was actively involved in raising the couple's now two-year-old son while tending to everyday household chores such as cleaning, performing yard work, running errands for the family and actively caring for the couple's young child. Moreover, prior to undergoing the Essure® procedure, Plaintiff was able to bring home income to help support her family.

332. As a direct and proximate result of these injuries, Plaintiff Long's spouse has been unable to perform the duties of a wife. Specifically, since being implanted with Essure®, Plaintiff Long's wife is no longer able to tend to everyday household chores such as cleaning, performing yard work, driving or running errands as a result of her constant severe pain. Plaintiff Long's wife is no longer able to pick-up the couple's now two-year-old son, which interferes with her parenting responsibilities.

333. Whereas Plaintiff Long's wife was once happy and healthy, she is now emotionally detached from Plaintiff Long as a result of her unexpected pregnancy, and experiences severe pain, stress and fatigue since being implanted with Essure®.

334. Whereas prior to undergoing the implantation of Essure®, Plaintiff and his wife enjoyed a healthy level of sexual intimacy, after Plaintiff Long's wife was implanted with Essure® the couple's sexual intimacy has sharply declined.

335. As a direct result of the injuries sustained by Plaintiff Long's wife and the severe physical and psychological strains they cause her to suffer, Plaintiff Long's wife is no longer able to provide him with the society and services, such as intimacy, companionship, affection, assistance, and support.

336. As a direct result of her injuries from the implantation of the Essure® device, Plaintiff Long's wife is unable to perform the duties as a wife in the future as she had prior to being implanted with Essure®, thereby depriving Plaintiff Long of his wife's society and services.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount according to proof at the time of trial;

2. Past and future economic and special damages according to proof at trial;

3. Loss of earnings and impaired earning capacity according to proof at trial;

4. Medical expenses, past and future, according to proof at the time of trial;

5. Equitable relief as the Court deems just and proper;

6. Declaratory judgment that Defendants are liable to Plaintiffs for all future evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendants' wrongdoing;

7. Medical monitoring, whether denominated as damages or in the form of equitable relief according to proof at the time of trial;

8. Punitive or exemplary damages according to proof at the time of trial;

9. Costs of suit incurred herein;

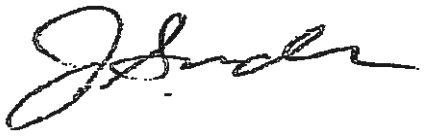
10. Pre-judgment interest as provided by law; and

11. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: May 5, 2016 By:



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